

"The Other City"
Efforts in DC
making an impact

Ending an epidemic
Strategy for an AIDS-
free generation by 2015

Prevention 101
The need for sexual
health education

**MEDIA
PLANET**

July 2012

HIV/AIDS AWARENESS

4

FACTS

ABOUT THE GLOBAL
HIV/AIDS EPIDEMIC

GOING THE EXTRA YARD

A champion on and off the field, New England Patriots quarterback
Tom Brady advocates for global HIV/AIDS awareness

PHOTO: J. TAYLOR EMERY

**VISION IS
MORE**
THAN THE ABILITY TO SEE.



VISIONING AN AIDS-FREE WORLD

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CHALLENGES

The world is at a “**defining moment**” in the AIDS epidemic.

Turning the tide on HIV

As the XIX International AIDS Conference (AIDS 2012) returns to the U.S. after a 22-year absence and convenes next week in Washington, D.C., it is time for bold action.

By the end of the day today, more than 7,000 people around the world will have been newly infected with HIV, joining the 34 million worldwide who are already living with this virus. In this country, nearly 50,000 people are newly infected with HIV each year, and since the beginning of the epidemic, approximately 600,000 have died of AIDS. In Washington, D.C., over 3 percent of residents are living with HIV/AIDS, a rate higher than the World Health Organization's definition of an epidemic.

Unprecedented progress

While the numbers are still staggering, for the first time in the history of this epidemic, we are in a position to turn the tide on HIV. We now know how to diag-

nose HIV with a simple blood test, treat it with efficient antiretroviral drug regimens, and eliminate transmission from a mother to her child.

While this progress should be acknowledged, we must also acknowledge the tremendous amount of work yet to be done. People living with HIV need to be diagnosed and begin treatment earlier in the course of their illness. Increasing education and reducing stigma faced by those living with and at risk for HIV will go a long way to achieving this goal. We need to expand HIV treatment for everyone in need around the world, which requires increased contributions from all governments and investments and participations of the community and private sector. There is no single magic bullet. We need to use a combination of prevention strategies to dramatically reduce the rate of new infections. This requires strategic program implementation and strengthening of health systems.



Diane V. Havlir, MD
Professor, Medicine at University of California San Francisco; Chief of HIV/AIDS Division, San Francisco General Hospital, U.S. Co-Chair, XIX International AIDS Conference

“While the numbers are still staggering, for the first time in the history of this epidemic, we are in a position to turn the tide on HIV.”

Continued development

We also need to continue to invest in research for a vaccine and a cure. Better drugs to treat HIV infection are in the pipeline and their continued development is crucial. These therapies can curb the epidemic, but ending the epidemic will require breakthroughs in vaccine and cure research and both avenues need robust support.

There is no better time for us to make a new commitment to change the course on HIV/AIDS, 31 years after it began. The theme of this year's conference—Turning the Tide Together—calls on all of us to harness our expertise, energy and resources to mount an effective and efficient response that can change the course of this epidemic. Our response at this critical moment will reflect on who we are. Action now will save lives and is an investment in health for the next generation. Let's seize this moment and not allow it to pass us by.

DIANE V. HAVLIR, MD

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FACT

1

34 MILLION
PEOPLE
WORLDWIDE
ARE LIVING
WITH HIV



WE RECOMMEND



Françoise Barré-Sinoussi
Co-discoverer of HIV; Director, Regulation of Retroviral Infections Unit, Institut Pasteur, Paris, France; IAS President-Elect

PAGE 4

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sharing
HOPE

INSPIRATION



GIVING BACK
Tom Brady visits children at a primary school in Accra, Ghana.
PHOTO: J. TAYLOR EMERY

FACT

2

MEDICINE THAT COSTS LESS THAN 50 CENTS PER DAY CAN HELP SAVE LIVES AFFECTED BY AIDS



NEWS IN BRIEF

Take control of your sexual health

Life continues after becoming HIV positive. Thanks to new treatments, many people with HIV are living longer, healthier lives and thriving. Sexual health—which is based on a positive and respectful approach to relationships and reproduction—remains important, too.

What exactly is sexual health? It is freedom from fear, shame, and violence. It's combating discrimination. It recognizes that pleasure is natural and desirable, and doesn't change simply because someone is HIV-positive. Sexual health involves respect and acceptance. We are human: Neither our worth nor our sexual health are defined or limited by a diagnosis.

A champion for AIDS in Africa

Tom Brady of the New England Patriots travels the world. Brady's got it all—good looks, great talent, money and a great future. Now, we learn he knows what less than 50 cents a day will buy: One life.

He has led his team to three Super Bowl championships. He has twice been named Super Bowl MVP. Some have said he is one of the best quarterbacks under pressure of all time. What many may not know about New England quarterback Tom Brady, however, is his advocacy for HIV/AIDS in Africa.

In 2007, Tom Brady visited Ghana and Uganda for eight days on a trip sponsored by ONE (the global advocacy organization co-founded by U2's Bono), where he toured health clinics, schools and other projects that are saving and transforming lives in Africa with

the support of U.S. government funding and international cooperation. Through his experience, he has learned that Americans can help save lives affected by AIDS with medicine that costs less than 50 cents a day per person. As a result of his trip, Brady has been actively involved in encouraging Americans to lobby Congress to support smart, effective programs that are saving millions of lives for less than one percent of the federal budget.

Making a difference

"Tom is more than a sports champion, he's a champion for Africa," said Tom Hart, U.S. executive director of ONE. "Over the years, he has been an important voice in bringing awareness to the global issues of extreme poverty and preventable disease. During his time on the ground in Africa, he saw how U.S. leadership is helping to improve—and save—lives."

Among the sites Brady visited were a women's micro credit program in Ghana, an elementary school in Uganda, and an Ugandan HIV/AIDS clinic partially funded by the President's Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund to Fight AIDS, Tuberculosis and Malaria.

A life-changing experience

"This was my first trip to Africa and it was an eye-opener," Brady said after the ONE trip. "I saw the best and brightest of the human spirit in the face of incredible poverty that most of us just can't comprehend. I've learned that we, as Americans, living in the greatest country in the world, can save innocent lives ravaged by AIDS with medicine that costs less than two quarters a day. When you see what CAN be done, it's impossible to not be driven to do more—the needs are still overwhelming. This won't be my last visit to

Africa and I hope to pass along what I've learned here to others who will listen."

Brady's trip inspired his continued involvement with ONE and advocacy on behalf of the world's poorest people. Recently, the New England Patriots quarterback was a supporter of ONE's (2015) QUILT, a digital AIDS quilt designed to bring people from all over the world together to fight for a historic achievement—the elimination of mother-to-child transmission of the disease, which would deliver the first AIDS-free generation in the more than 30 years since the virus was first diagnosed. He also supports ONE's activities on college campuses to raise awareness among young people of extreme poverty and preventable disease.

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Globally, an estimated
3,000
young people
are infected with HIV
each day.

INSPIRATION

QUESTION & ANSWER



Françoise Barré-Sinoussi,
Co-discoverer of HIV,
Director of the Regulation of Retroviral Infections Unit at the Institut Pasteur in Paris and the IAS President-Elect

■ How did you discover the HIV virus?

Shortly after the first cases of AIDS were described, a group of French clinicians contacted our team of retrovirologists to explore whether a retrovirus was responsible for this new disease. Together, we decided to look for a retroviral activity in cells coming from a lymph node of a patient at risk of AIDS using a classical approach. In early 1983, we detected a reverse transcriptase activity and further analysis showed we were dealing with a new human retrovirus.

■ Are you hopeful we will find a cure for HIV in the near future? Why?

I am always hopeful. Recent scientific evidences have been telling us that a cure might be achievable. The “Berlin Patient,” the first man to be cured of AIDS, has provided scientists with a “proof of concept” of a functional cure. We are starting to better understand HIV latency and how natural control of the infection can be achieved.

FRANÇOISE BARRÉ-SINOUSSE
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The unseen city speaks up

■ **Question:** What do people living with HIV/AIDS do when the agencies tasked to help them are unresponsive to their needs?

■ **Answer:** Get involved.

The documentary *The Other City* helped open the nation’s eyes to HIV/AIDS rates in its own capital that rivaled the rates in many African countries.

“We came to understand how HIV/AIDS intersects and reflects many of the injustices and inequities that plague our capital and our nation, including health care disparities, poverty, and [lack of] education,” says the film’s director Susan Koch.

The Other City is part wake-up call to government and part tribute to the people who struggle to deal with the complex web of problems created by living with HIV/AIDS.

Faces behind statistics

In the film, J’Mia Edwards, who has AIDS, describes how her illness affects her family, “[My kids] keep thinking I’m going to die tomorrow. I keep telling them, I’m too stubborn to die, and that I’m going to be OK, as long as I take my medication.

The children were right to be concerned. AIDS is the leading



FINDING HOPE
J’Mia Edwards, a young mother living with AIDS, fights to keep housing for her three young children.
PHOTO: JONAH KOCH / CABIN FILMS

cause of death for black women ages 25-34. But Edwards’ concerns were more than medical. After learning that she was being evicted from her apartment when the city’s AIDS office changed providers, she discovered that the waiting list for subsidized housing for people living with HIV/AIDS was two to three years.

“Housing is my prevention. Without housing, I couldn’t take my medication, because my medication must be refrigerated,” Edwards explained at a press conference. Edwards was frustrated with government agencies, “I feel like I’m slipping through the

cracks. I feel like they [are] leaving us out to dry.”

Edwards is stubborn, though. She did not slip gently between any cracks. She educated herself about HIV/AIDS and the social and political system she would have to work with in order to take care of herself and her children, found full-time work as an HIV testing counselor, and eventually a better apartment for herself and her children.

Hope

Edwards, and the other individuals profiled in *The Other City*, “are focusing beyond their own

circumstances living with HIV/AIDS, and are working to make their communities healthier and safer. I have never met such caring, committed individuals and it gives me great hope that we can end AIDS in America,” says Koch.

Washington, D. C. still has one of the highest HIV/AIDS rates in the nation, but its leaders are no longer blind to the problem. Edwards and other citizens of “the other city” have made sure of that.

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ASHA is America’s authority for information on sexual health. Founded in 1914, ASHA is an award-winning and trusted non-profit that specializes in accurate and unbiased sexual health information.

www.ashastd.org

NEWS

Global and national strategies to prevent and fight HIV/AIDS

■ **Question:** Why is HIV/AIDS awareness and testing so vital?

■ **Answer:** Because over half of all people living with HIV don't even know they have the disease.

It's been 30 years since AIDS was identified, and in that time a lot of progress has been made. Nationally and globally, efforts are underway to provide treatment for those diagnosed and to prevent the spread of the disease.

Global AIDS strategy

According to Michel Sidibé, the Executive Director of the Joint United Nations Programme on HIV/AIDS (UNAIDS) and Under-Secretary-General of the United Nations, the AIDS epidemic peaked in 1999.

Since then, AIDS programs have expanded worldwide and rates of new HIV infections have fallen in most of the world.

"HIV is no longer seen as a death sentence, but as a condition that can be managed," explains Sidibé.

Lowering costs for treatments is a goal, as is increased sustainability, since funding for AIDS

research and treatment changes every year.

Awareness and testing are also priorities since "half of all people living with HIV do not know that they have the virus," says Sidibé, who believes testing needs to be simplified and have immediate results.

UNAIDS' vision is to "Get to Zero," which Sidibé says "is about achieving zero new HIV infections, zero discrimination and zero AIDS-related deaths."

Part of this strategy is about stopping new infections in children. "The strategy focuses on the 22 countries, most in sub-Saharan Africa, which account for 90 percent of all new HIV infections in children," says Sidibé.

"HIV is no longer seen as a death sentence, but as a condition that can be managed."

In **2003** only 400,000 people had access to the lifesaving treatment.

Today that number has risen to 8 million.

The scale up from 2010-2011 alone was **1.4 million—an increase of 20% in just one year.**

It's working: UNAIDS is already seeing about a 25 percent reduction in new infections in children in the last two years.

U.S. efforts

About 1.2 million Americans have HIV and each year about 50,000 more become infected.

President Barack Obama has expanded The President's Emergency Plan for AIDS Relief (PEPFAR) and he's launched The National HIV/AIDS Strategy, with a goal of meeting "clear and measurable targets" by 2015.

Among the targets: reaching over 1.5 million HIV-positive pregnant women with antiretroviral drugs to prevent passing HIV to their babies; supporting over 4.7

million voluntary male circumcisions in Eastern and Southern Africa to reduce the female to male transmission of HIV; and distributing more than a billion condoms.

"Scientific advances, funded in large part by the United States, have made it possible to set our sights on creating an AIDS-free generation," writes Dr. Grant Colfax, Director of the Office of National AIDS Policy, in a recent blog. "To achieve this goal, we must all share in the responsibility to make smart investments that will improve and save even more lives."

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QUESTION & ANSWER



Dr. Elly Tebasoboke Katabira,
President,
International
AIDS Society
(IAS)

■ **How important has the United States government funding of the global AIDS response been in your own experience?**

The International AIDS Society congratulates the U.S. government on its enormous commitment to addressing the global HIV/AIDS epidemic, particularly through the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). Since 2004 PEPFAR has put more than \$30 billion into funding to fight the AIDS epidemic—the largest financial commitment by a single country to responding to HIV and AIDS worldwide.

■ **How can we continue to advance our nation's response to the global AIDS epidemic?**

Three words: funding, political will and scientific investigation. Studies presented at the July 2009 International AIDS Society conference in Cape Town showed that investments in fighting HIV/AIDS, including those of PEPFAR, contributed to population-level reductions in child and infant mortality. For example, in my native Eastern Uganda, the increase in HIV and AIDS services is associated with an 83 percent reduction in non HIV-related infant mortality.

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Contribute **3 condoms** to Haiti for every 1 purchased
IN SUPPORT OF **AIDS 2012 CONFERENCE**, PURCHASE SIR RICHARD'S
& RECEIVE 10% OFF. CODE: **PREVENTION2012 ***

* Offer redeemed at sirrichards.com and expires on July 31, 2012.
Condoms to be made available at Partners In Health's clinics in 2013.



ABOUT PREZISTA®

PREZISTA® (darunavir) is a prescription medicine. It is one treatment option in the class of HIV (human immunodeficiency virus) medicines known as protease inhibitors.

PREZISTA® is always taken with and at the same time as ritonavir (Norvir®), in combination with other HIV medicines for the treatment of HIV infection in adults. PREZISTA® should also be taken with food.

- The use of other medicines active against HIV in combination with PREZISTA®/ritonavir (Norvir®) may increase your ability to fight HIV. Your healthcare professional will work with you to find the right combination of HIV medicines
- It is important that you remain under the care of your healthcare professional during treatment with PREZISTA®

PREZISTA® does not cure HIV infection or AIDS and you may continue to experience illnesses associated with HIV-1 infection, including opportunistic infections. You should remain under the care of a doctor when using PREZISTA®

Please read Important Safety Information below, and talk to your healthcare professional to learn if PREZISTA® is right for you.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about PREZISTA®?

- **PREZISTA® can interact with other medicines and cause serious side effects. See “Who should not take PREZISTA®?”**
- **PREZISTA® may cause liver problems.** Some people taking PREZISTA®, together with Norvir® (ritonavir), have developed liver problems which may be life-threatening. Your healthcare professional should do blood tests before and during your combination treatment with PREZISTA®. If you have chronic hepatitis B or C infection, your healthcare professional should check your blood tests more often because you have an increased chance of developing liver problems
- Tell your healthcare professional if you have any of these signs and symptoms of liver problems: dark (tea-colored) urine, yellowing of your skin or whites of your eyes, pale-colored stools (bowel movements), nausea, vomiting, pain or tenderness on your right side below your ribs, or loss of appetite
- **PREZISTA® may cause a severe or life-threatening skin reaction or rash.** Sometimes these skin reactions and skin rashes can become severe and require treatment in a hospital. You should call your healthcare professional immediately if you develop a rash. However, **stop** taking PREZISTA® and ritonavir combination treatment and call your healthcare professional immediately if you develop any skin changes with these symptoms: fever, tiredness, muscle or joint pain, blisters or skin lesions, mouth sores or ulcers, red or inflamed eyes, like “pink eye.” Rash occurred more often in patients taking PREZISTA® and raltegravir together than with either drug separately, but was generally mild

Who should not take PREZISTA®?

- **Do not take PREZISTA® if you are taking the following medicines:** alfuzosin (Uroxatral®), dihydroergotamine (D.H.E.45®, Embolex®, Migranal®), ergonovine, ergotamine (Cafergot®, Ergomar®), methylegonovine, cisapride (Propulsid®), pimozide (Orap®), oral midazolam, triazolam (Halcion®), the herbal supplement St. John’s wort (*Hypericum perforatum*), lovastatin (Mevacor®, Altoprev®, Advicor®), simvastatin (Zocor®, Simcor®, Vytorin®), rifampin (Rifadin®, Rifater®,

Rifamate®, Rimactane®), sildenafil (Revatio®) when used to treat pulmonary arterial hypertension, indinavir (Crixivan®), lopinavir/ritonavir (Kaletra®), saquinavir (Invirase®), boceprevir (Victrelis™), or telaprevir (Incivek™)

- Before taking PREZISTA®, tell your healthcare professional if you are taking sildenafil (Viagra®, Revatio®), vardenafil (Levitra®, Staxyn®), tadalafil (Cialis®, Adcirca®), atorvastatin (Lipitor®), rosuvastatin (Crestor®), pravastatin (Pravachol®), or colchicine (Colcris®, Col-Probenecid®). Tell your healthcare professional if you are taking estrogen-based contraceptives (birth control). PREZISTA® might reduce the effectiveness of estrogen-based contraceptives. You must take additional precautions for birth control, such as condoms

This is not a complete list of medicines. Be sure to tell your healthcare professional about all the medicines you are taking or plan to take, including prescription and nonprescription medicines, vitamins, and herbal supplements.

What should I tell my doctor before I take PREZISTA®?

- Before taking PREZISTA®, tell your healthcare professional if you have any medical conditions, including liver problems (including hepatitis B or C), allergy to sulfa medicines, diabetes, or hemophilia
- Tell your healthcare professional if you are pregnant or planning to become pregnant, or are breastfeeding
 - The effects of PREZISTA® on pregnant women or their unborn babies are not known. You and your healthcare professional will need to decide if taking PREZISTA® is right for you
 - **Do not breastfeed.** It is not known if PREZISTA® can be passed to your baby in your breast milk and whether it could harm your baby. Also, mothers with HIV should not breastfeed because HIV can be passed to your baby in the breast milk

What are the possible side effects of PREZISTA®?

- High blood sugar, diabetes or worsening of diabetes, and increased bleeding in people with hemophilia have been reported in patients taking protease inhibitor medicines, including PREZISTA®
- Changes in body fat have been seen in some patients taking HIV medicines, including PREZISTA®. The cause and long-term health effects of these conditions are not known at this time
- Changes in your immune system can happen when you start taking HIV medicines. Your immune system may get stronger and begin to fight infections that have been hidden
- The most common side effects related to taking PREZISTA® include diarrhea, nausea, rash, headache, stomach pain, and vomiting. This is not a complete list of all possible side effects. If you experience these or other side effects, talk to your healthcare professional. Do not stop taking PREZISTA® or any other medicines without first talking to your healthcare professional

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please refer to the ritonavir (Norvir®) Product Information (PI and PPI) for additional information on precautionary measures.

Please read accompanying Patient Information for PREZISTA® and discuss any questions you have with your doctor.

A man with short dark hair and a light beard is smiling. He is wearing a bright green zip-up track jacket with dark blue stripes on the sleeves and a dark blue collar. He is also wearing dark blue jeans. His hands are in his pockets.

IS THE PREZISTA[®] EXPERIENCE RIGHT FOR YOU?

There is no other person in the world who is exactly like you. And no HIV treatments are exactly alike, either. That's why you should ask your healthcare professional about PREZISTA[®] (darunavir).

Once-Daily PREZISTA[®] taken with ritonavir and in combination with other HIV medications can help lower your viral load and keep your HIV under control over the long term.

In a clinical study* of almost 4 years (192 weeks), 7 out of 10 adults who had never taken HIV medications before maintained undetectable[†] viral loads with PREZISTA[®] plus ritonavir and Truvada[®].

**Find out if the PREZISTA[®] EXPERIENCE is right for you.
Ask your healthcare professional and learn more
at ExplorePREZISTA.com**

*Please read the Important Safety Information and
Patient Information on adjacent pages.*

The logo consists of a stylized human figure in blue and green, with arms raised in a 'V' shape.

PREZISTA[®]
(darunavir) tablets



**Snap a quick pic of our logo to show your
doctor and get the conversation started.**

*A randomized open label Phase 3 trial comparing PREZISTA[®]/ritonavir 800/100 mg once daily (n=343) vs. Kaletra[®]/ritonavir 800/200 mg/day (n=346).

[†]Undetectable was defined as a viral load of less than 50 copies per mL.
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IMPORTANT PATIENT INFORMATION

PREZISTA (pre-ZIS-ta)

(darunavir)

Oral Suspension

PREZISTA (pre-ZIS-ta)

(darunavir)

Tablets

Read this Patient Information before you start taking PREZISTA and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

Also read the Patient Information leaflet for NORVIR® (ritonavir).

What is the most important information I should know about PREZISTA?

- **PREZISTA can interact with other medicines and cause serious side effects.** It is important to know the medicines that should not be taken with PREZISTA. See the section “**Who should not take PREZISTA?**”
- **PREZISTA may cause liver problems.** Some people taking PREZISTA in combination with NORVIR® (ritonavir) have developed liver problems which may be life-threatening. Your healthcare provider should do blood tests before and during your combination treatment with PREZISTA. If you have chronic hepatitis B or C infection, your healthcare provider should check your blood tests more often because you have an increased chance of developing liver problems.
- Tell your healthcare provider if you have any of the below signs and symptoms of liver problems.
 - Dark (tea colored) urine
 - yellowing of your skin or whites of your eyes
 - pale colored stools (bowel movements)
 - nausea
 - vomiting
 - pain or tenderness on your right side below your ribs
 - loss of appetite

PREZISTA may cause severe or life-threatening skin reactions or rash. Sometimes these skin reactions and skin rashes can become severe and require treatment in a hospital. You should call your healthcare provider immediately if you develop a rash. However, **stop** taking PREZISTA and ritonavir combination treatment and call your healthcare provider immediately if you develop any skin changes with symptoms below:

- fever
- tiredness
- muscle or joint pain
- blisters or skin lesions
- mouth sores or ulcers
- red or inflamed eyes, like “pink eye” (conjunctivitis)

Rash occurred more often in patients taking PREZISTA and raltegravir together than with either drug separately, but was generally mild.

See “**What are the possible side effects of PREZISTA?**” for more information about side effects.

What is PREZISTA?

PREZISTA is a prescription anti-HIV medicine used with ritonavir and other anti-HIV medicines to treat adults with human immunodeficiency virus (HIV-1) infection. PREZISTA is a type of anti-HIV medicine called a protease inhibitor. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

When used with other HIV medicines, PREZISTA may help to reduce the amount of HIV in your blood (called “viral load”). PREZISTA may also help to increase the number of white blood cells called CD4 (T) cell which help fight off other infections. Reducing the amount of HIV and increasing the CD4 (T) cell count may improve your immune system. This may reduce your risk of death or infections that can happen when your immune system is weak (opportunistic infections).

PREZISTA does not cure HIV infection or AIDS and you may continue to experience illnesses associated with HIV-1 infection, including opportunistic infections. You should remain under the care of a doctor when using PREZISTA.

Avoid doing things that can spread HIV-1 infection.

- **Do not share needles or other injection equipment.**
- **Do not share personal items that can have blood or body fluids on them, like toothbrushes and razor blades.**
- **Do not have any kind of sex without protection.** Always practice safe sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.

Ask your healthcare provider if you have any questions on how to prevent passing HIV to other people.

Who should not take PREZISTA?

Do not take PREZISTA with any of the following medicines:

- alfuzosin (Uroxatral®)
- dihydroergotamine (D.H.E. 45®, Embolex®, Migranal®), ergonovine, ergotamine (Cafegot®, Ergomar®) methylergonovine
- cisapride
- pimozone (Orap®)
- oral midazolam, triazolam (Halcion®)
- the herbal supplement St. John’s Wort (*Hypericum perforatum*)
- the cholesterol lowering medicines lovastatin (Mevacor®, Altoprev®, Advicor®) or simvastatin (Zocor®, Simcor®, Vytorin®)
- rifampin (Rifadin®, Rifater®, Rifamate®, Rimactane®)
- sildenafil (Revatio®) only when used for the treatment of pulmonary arterial hypertension.

Serious problems can happen if you take any of these medicines with PREZISTA.

What should I tell my doctor before I take PREZISTA?

PREZISTA may not be right for you. Before taking PREZISTA, tell your healthcare provider if you:

- have liver problems, including hepatitis B or hepatitis C
- are allergic to sulfa medicines
- have high blood sugar (diabetes)

- have hemophilia
- are pregnant or planning to become pregnant. It is not known if PREZISTA will harm your unborn baby. **Pregnancy Registry:** You and your healthcare provider will need to decide if taking PREZISTA is right for you. If you take PREZISTA while you are pregnant, talk to your healthcare provider about how you can be included in the Antiretroviral Pregnancy Registry. The purpose of the registry is follow the health of you and your baby.
- are breastfeeding or plan to breastfeed. **Do not breastfeed.** We do not know if PREZISTA can be passed to your baby in your breast milk and whether it could harm your baby. Also, mothers with HIV-1 should not breastfeed because HIV-1 can be passed to the baby in the breast milk.

Tell your healthcare provider about all the medicines you take including prescription and nonprescription medicines, vitamins, and herbal supplements. Using PREZISTA and certain other medicines may affect each other causing serious side effects. PREZISTA may affect the way other medicines work and other medicines may affect how PREZISTA works.

Especially tell your healthcare provider if you take:

- medicine to treat HIV
- estrogen-based contraceptives (birth control). PREZISTA might reduce the effectiveness of estrogen-based contraceptives. You must take additional precautions for birth control such as a condom.
- medicine for your heart such as bepridil, lidocaine (Xylocaine Viscous®), quinidine (Nuedexta®), amiodarone (Pacerone®, Cardarone®), digoxin (Lanoxin®), flecainide (Tambacor®), propafenone (Rythmol®)
- warfarin (Coumadin®, Jantoven®)
- medicine for seizures such as carbamazepine (Carbatrol®, Equetro®, Tegretol®, Epitol®), phenobarbital, phenytoin (Dilantin®, Phenytek®)
- medicine for depression such as trazadone and desipramine (Norpramin®)
- clarithromycin (Prevpac®, Biaxin®)
- medicine for fungal infections such as ketoconazole (Nizoral®), itraconazole (Sporanox®, Onmel®), voriconazole (Vfend®)
- colchicine (Colcrys®, Col-Probenecid®)
- rifabutin (Mycobutin®)
- medicine used to treat blood pressure, a heart attack, heart failure, or to lower pressure in the eye such as metoprolol (Lopressor®, Toprol-XL®), timolol (Cosopt®, Betimol®, Timoptic®, Isatolol®, Combigan®)
- midazolam administered by injection
- medicine for heart disease such as felodipine (Plendil®), nifedipine (Procardia®, Adalat CC®, Afeditab CR®), nicardipine (Cardene®)
- steroids such as dexamethasone, fluticasone (Advair Diskus®, Veramyst®, Flovent®, Flonase®)
- bosentan (Tracleer®)
- medicine to treat chronic hepatitis C such as boceprevir (Victrelis™), telaprevir (Incivek™)
- medicine for cholesterol such as pravastatin (Pravachol®), atorvastatin (Lipitor®), rosuvastatin (Crestor®)

IMPORTANT PATIENT INFORMATION

- medicine to prevent organ transplant failure such as cyclosporine (Gengraf[®], Sandimmune[®], Neoral[®]), tacrolimus (Prograf[®]), sirolimus (Rapamune[®])
- salmeterol (Advair[®], Serevent[®])
- medicine for narcotic withdrawal such as methadone (Methadose[®], Dolophine Hydrochloride), buprenorphine (Butrans[®], Buprenex[®], Subutex[®]), buprenorphine/naloxone (Suboxone[®])
- medicine to treat schizophrenia such as risperidone (Risperdal[®]), thioridazine
- medicine to treat erectile dysfunction or pulmonary hypertension such as sildenafil (Viagra[®], Revatio[®]), vardenafil (Levitra[®], Staxyn[®]), tadalafil (Cialis[®], Adcirca[®])
- medicine to treat anxiety, depression or panic disorder such as sertraline (Zoloft[®]), paroxetine (Paxil[®])

This is **not** a complete list of medicines that you should tell your healthcare provider that you are taking. Ask your healthcare provider or pharmacist if you are not sure if your medicine is one that is listed above. Know the medicines you take. Keep a list of them to show your doctor or pharmacist when you get a new medicine. Do not start any new medicines while you are taking PREZISTA without first talking with your healthcare provider.

How should I take PREZISTA?

- Take PREZISTA every day exactly as prescribed by your healthcare provider.
- You must take ritonavir (NORVIR[®]) at the same time as PREZISTA.
- Do not change your dose of PREZISTA or stop treatment without talking to your healthcare provider first.
- Take PREZISTA and ritonavir (NORVIR[®]) with food.
- Swallow PREZISTA tablets whole with a drink. If you have difficulty swallowing PREZISTA tablets, PREZISTA oral suspension is also available. Your health care provider will help determine whether PREZISTA tablets or oral suspension is right for you.
- PREZISTA oral suspension should be given with the supplied oral dosing syringe. Shake the suspension well before each usage.
- If you take too much PREZISTA, call your healthcare provider or go to the nearest hospital emergency room right away.

What should I do if I miss a dose?

People who take PREZISTA one time a day:

- If you miss a dose of PREZISTA by less than 12 hours, take your missed dose of PREZISTA right away. Then take your next dose of PREZISTA at your regularly scheduled time.
- If you miss a dose of PREZISTA by more than 12 hours, wait and then take the next dose of PREZISTA at your regularly scheduled time.

People who take PREZISTA two times a day

- If you miss a dose of PREZISTA by less than 6 hours, take your missed dose of PREZISTA right away. Then take your next dose of PREZISTA at your regularly scheduled time.

- If you miss a dose of PREZISTA by more than 6 hours, wait and then take the next dose of PREZISTA at your regularly scheduled time.

If a dose of PREZISTA is skipped, do not double the next dose. Do not take more or less than your prescribed dose of PREZISTA at any one time.

What are the possible side effects of PREZISTA?

PREZISTA can cause side effects including:

- See **“What is the most important information I should know about PREZISTA?”**
- **Diabetes and high blood sugar (hyperglycemia).** Some people who take protease inhibitors including PREZISTA can get high blood sugar, develop diabetes, or your diabetes can get worse. Tell your healthcare provider if you notice an increase in thirst or urinate often while taking PREZISTA.
- **Changes in body fat.** These changes can happen in people who take antiretroviral therapy. The changes may include an increased amount of fat in the upper back and neck (“buffalo hump”), breast, and around the back, chest, and stomach area. Loss of fat from the legs, arms, and face may also happen. The exact cause and long-term health effects of these conditions are not known.
- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Call your healthcare provider right away if you start having new symptoms after starting your HIV medicine.
- **Increased bleeding for hemophiliacs.** Some people with hemophilia have increased bleeding with protease inhibitors including PREZISTA.

The most common side effects of PREZISTA include:

- diarrhea
- nausea
- rash
- headache
- abdominal pain
- vomiting

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of PREZISTA. For more information, ask your health care provider.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

How should I store PREZISTA?

- Store PREZISTA oral suspension and tablets at room temperature [77°F (25°C)].
- Do not refrigerate or freeze PREZISTA oral suspension.
- Keep PREZISTA away from high heat.
- PREZISTA oral suspension should be stored in the original container.

Keep PREZISTA and all medicines out of the reach of children.

General information about PREZISTA

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use PREZISTA for a condition for which it was not prescribed. Do not give PREZISTA to other people even if they have the same condition you have. It may harm them.

This leaflet summarizes the most important information about PREZISTA. If you would like more information, talk to your healthcare provider. You can ask your healthcare provider or pharmacist for information about PREZISTA that is written for health professionals.

For more information, call 1-800-526-7736.

What are the ingredients in PREZISTA?

Active ingredient: darunavir

Inactive ingredients:

PREZISTA Oral Suspension: hydroxypropyl cellulose, microcrystalline cellulose, sodium carboxymethylcellulose, methylparaben sodium, citric acid monohydrate, sucralose, masking flavor, strawberry cream flavor, hydrochloric acid (for pH adjustment), purified water.

PREZISTA 75 mg and 150 mg Tablets: colloidal silicon dioxide, crospovidone, magnesium stearate, microcrystalline cellulose. The film coating contains: OPADRY[®] White (polyethylene glycol 3350, polyvinyl alcohol-partially hydrolyzed, talc, titanium dioxide).

PREZISTA 400 mg and 600 mg Tablets: colloidal silicon dioxide, crospovidone, magnesium stearate, microcrystalline cellulose. The film coating contains: OPADRY[®] Orange (FD&C Yellow No. 6, polyethylene glycol 3350, polyvinyl alcohol-partially hydrolyzed, talc, titanium dioxide).

This Patient Information has been approved by the U.S Food and Drug Administration.

Manufactured by:
PREZISTA Oral Suspension
Janssen Pharmaceutica, N.V.
Beerse, Belgium

PREZISTA Tablets
Janssen Ortho LLC, Gurabo, PR 00778

Manufactured for:
Janssen Therapeutics, Division of Janssen Products, LP, Titusville NJ 08560

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PREZISTA[®] is a registered trademark of Janssen Pharmaceuticals

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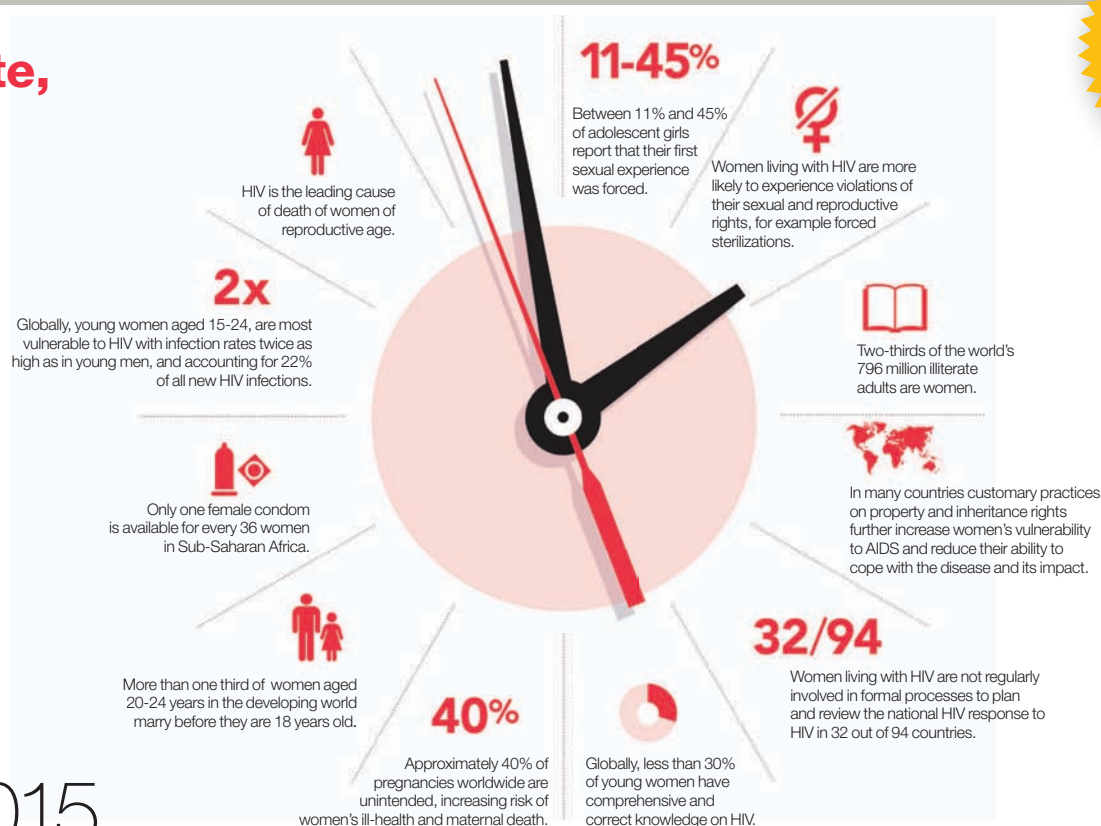
Revised: May 2012



INSIGHT

Every minute, a young woman is newly infected with HIV.

As a result of their lower economic, socio-cultural status in many countries, women and girls are disadvantaged when it comes to negotiating safe sex, and accessing HIV prevention information and services.



SOURCE: UNAIDS

Ensuring an AIDS-free generation by 2015



Deborah Dugan
Chief Executive
Officer, (RED)

How many children each year are born with HIV both in the U.S. and globally?

Globally, an estimated 390,000 children were newly infected with HIV in 2010, down 30 percent from the peak of the global epidemic in 1997, based on the UNAIDS World AIDS Day Report, 2011. Approximately 100-200 babies are born with HIV each year in the United States, according to The Elizabeth Glaser Pediatric AIDS Foundation.

What can be done to prevent mother-to-child transmission as a nation? Globally?

More than 1,000 babies are born every day with HIV when this is nearly entirely preventable with

access to the right treatment. The medicines exist to stop mother-to-child transmission of HIV and to ensure that all children are born HIV-free, but in order to achieve the 2015 goal of virtually ending mother-to-child transmission of the virus, we must get 1.4 million HIV-positive pregnant women and their babies access to effective antiretroviral treatment during pregnancy and breastfeeding, with costs as low as 40 cents a day. Political leadership that prioritizes this issue—within donor countries and the private sector, but even more importantly, in countries with high levels of mother-to-child transmission—is also key.

How close are we to reaching the goal of an AIDS-free generation by 2015? What more can be done to ensure we meet this goal?

Thanks to the efforts of the last decade and recent scientific advances, the virtual elimination

of mother-to-child transmission and the beginning of the end of AIDS are both possible, but significant work still needs to be done. We find ourselves in a time when the global economy threatens public sector funding. For (RED)'s part, we are working to create massive heat and awareness around the 2015 goal, as well as generate critically needed private sector funds for the Global Fund. Innovative financing solutions and the combined efforts of the public and private sectors as well as individuals are key to maintaining this fight in the current environment. Working together, we can bring an end to AIDS. It's a remarkable, critical opportunity that we simply cannot afford to miss.

DEBORAH DUGAN

editorial@mediaplanet.com

**AIDS
free
generation?**

Not without women.

We can't turn the tide on HIV/AIDS without women.

CHANGE
CENTER FOR HEALTH
AND GENDER EQUITY

It's time for a woman-centered approach to HIV/AIDS. Take action at www.genderhealth.org

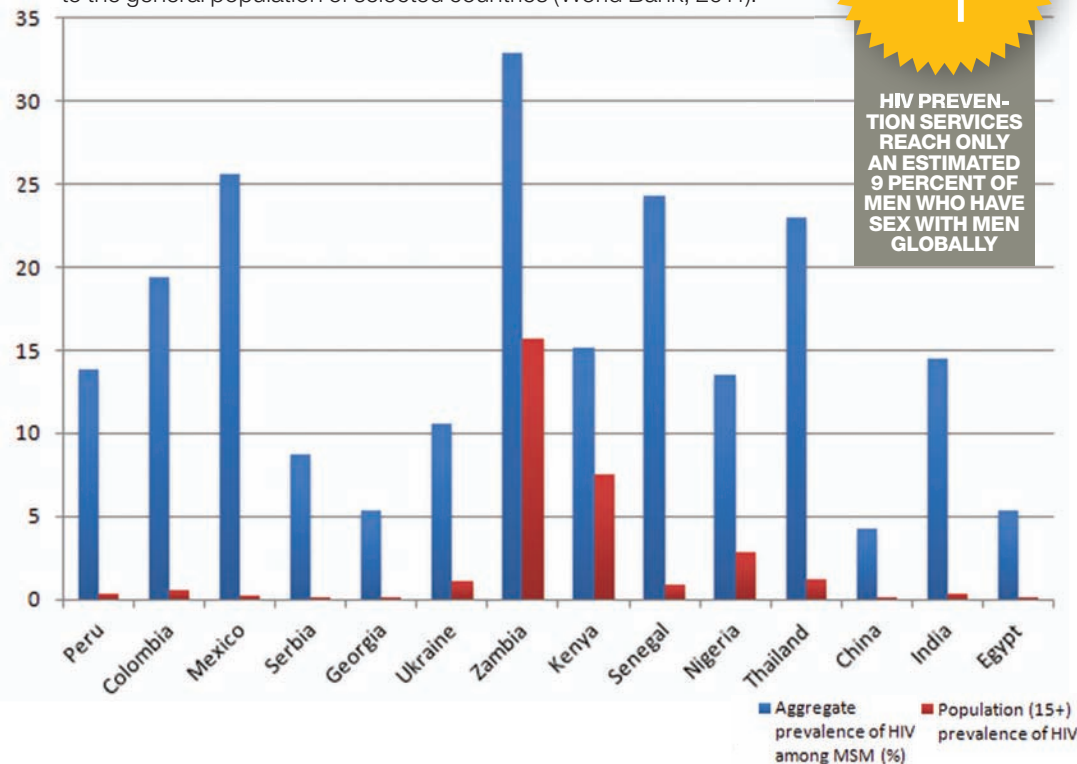
CFC # 62113

PHOTO FOR ILLUSTRATIVE PURPOSES ONLY.

NEWS

More than
60%
of new HIV/AIDS
infections are found
in gay men

HIV prevalence rates among men who have sex with men compared to the general population of selected countries (World Bank, 2011).



FACT

4

HIV PREVENTION SERVICES REACH ONLY AN ESTIMATED 9 PERCENT OF MEN WHO HAVE SEX WITH MEN GLOBALLY

Amid stigma and apathy, gay men confront the global AIDS crisis

The United States will host the International AIDS Conference this summer, spotlighting a national epidemic in which gay men account for more than half of all people living with HIV and more than 60 percent of new infections.

Contrary to popular misconceptions, these dynamics are not unique to high-income countries like the United States. HIV rates are skyrocketing among gay men and other men who have sex with men (MSM) across every world region.

Despite clear evidence that calls for intervention, gay men and other MSM have not been prioritized in the global effort against AIDS. Only an estimated two percent of the global HIV prevention budget is directed at MSM.

“MSM around the world face pervasive social and structural barriers such as stigma, dis-

crimination and human rights violations,” said Dr. George Ayala, Executive Director of the Global Forum on MSM and HIV (MSMGF). “At all levels of the AIDS response, it has been politically easier to ignore these barriers and develop more generic approaches, hoping that MSM will somehow get the services they need. Clearly this strategy has failed.”

Taking a stand

Faced with inaction from public health authorities, gay communities around the world have organized their own grassroots efforts to fight HIV. The people behind these efforts are often highly motivated, creative and have a deep understanding of their local context. However, most of this work is done with little to no funding, and because homosexuality outlawed in nearly 80 countries, many advocates risk violence and



“Today, we have more tools to tackle the epidemic than at any other point in history.”

Dr. George Ayala
Executive Director, MSMGF

imprisonment to provide lifesaving services to gay men.

“We are doing this work because our friends are dying,” said Sam Matsikure, program manager at Gays and Lesbians of Zimbabwe (GALZ). “There is no sexual health information to help MSM understand their risk factors, and many of us who are HIV-positive refuse to seek care because of how we are treated in clinics and hospitals. Advocates are supposed to meet all of these needs, all while our

offices are raided by the police? This is extremely challenging work.”

Making history

As this year’s International AIDS Conference approaches, recent scientific advances in pre-exposure prophylaxis and treatment as prevention have led some to herald a turning point in the global response to HIV. “For the first time we have a real opportunity to make a major dent in the

epidemic,” said Dr. Elly Katabira, President of the International AIDS Society.

However, some advocates question whether these goals can be achieved without more focused efforts among MSM and other “key” populations, like sex workers, people who use drugs, and transgender people—communities with high HIV-burden who face similar barriers.

“Today, we have more tools to tackle the epidemic than at any other point in history,” said Dr. Ayala. “And the community response is more robust than ever before. Now we must work to hold governments accountable and ensure that impacted communities have the support and legal protections they need to meet these challenges. This is the only way we will end the epidemic.”

JACK BECK

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The Fenway Institute at Fenway Health is an interdisciplinary center for research, training, education, and policy development, focusing on national and international health issues. Our mission is to ensure access to quality, culturally competent medical and mental health care for traditionally underserved communities, including lesbian, gay, bisexual and transgender (LGBT) people and those affected by HIV/AIDS. The Fenway Institute is at the center of some of the most promising and relevant HIV research being conducted today.

Visit us online at www.thefenwayinstitute.org to learn more