PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

PREZISTA® 600 mg (film-coated tablet)

Read this entire leaflet carefully before you start taking PREZISTA.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- PREZISTA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT PREZISTA CONTAINS

Each film-coated tablet contains 600 mg of darunavir as ethanolate salt.

The other ingredients are:

Colloidal silicon dioxide, crospovidone, macrogol, magnesium stearate, microcrystalline cellulose, polyvinyl alcohol (partially hydrolysed), talc and titanium dioxide (C.I. no. 77891).

Sugar free

WHAT PREZISTA IS USED FOR

PREZISTA is an antiretroviral medicine. It belongs to a group called protease inhibitors.

PREZISTA works by reducing the amount of human immunodeficiency virus (HIV) in your body. This will improve your immune system and reduce the risk of developing illnesses linked to HIV infection.

PREZISTA is used in combination with ritonavir and other antiretroviral medicines to treat adults who are infected with HIV and who have developed resistance to other antiretroviral medicines.

Your doctor will discuss with you which combination of medicines is best for you.

BEFORE YOU TAKE PREZISTA

Do not take PREZISTA:

- if you are **allergic** (hypersensitive) to darunavir, other ingredients of PREZISTA or to ritonavir.

Do not take PREZISTA with any of the following medicines:

- medicines to treat convulsions (epilepsy) (*carbamazepine, phenobarbital or phenytoin*).
- medicines to treat allergy symptoms (astem*izole*).
- medicines to treat tuberculosis (*rifampicin*).
- medicines to treat high blood pressure as a result of problems with your lungs (*sildenafil*).
- medicines to treat prostate problems (*alfuzosin*).
- medicines to treat migraine and headaches (*dihydroergotamine, ergonovine, ergotamine, methylergonovine*).
- herbal products containing St. John's Wort (e.g. for depression).
- medicines to treat high cholesterol (*lovastatin or simvastatin*).

- medicines to treat psychiatric conditions such as schizophrenia (*pimozide*).
- medicines to treat trouble with sleeping and/or anxiety (*midazolam or triazolam*).
- medicines to treat fungal infections (*ketoconazole, itraconazole and voriconazole*).
- medicines to treat narcotic dependance (*buprenorphine/naloxone*).

If you are taking any of these, discuss it with your doctor.

Take special care with PREZISTA

PREZISTA must be taken together with ritonavir and food. PREZISTA is not a cure for HIV infection. PREZISTA does not reduce the risk of passing HIV to others through sexual contact or blood contaminations. Therefore, you must continue to use appropriate precautions, such as condoms.

People taking PREZISTA may still develop infections or other illnesses associated with HIV infection. You must keep in regular contact with your doctor.

Contact your doctor immediately if the following is experienced:

- severe rash.
- sulphonamide (antimicrobial used to treat certain infections) allergy.

Make sure that you check the following points and tell your doctor if any of these apply to you:

- Tell your doctor if you have had **problems with your liver** before. Your doctor may evaluate how severe your liver disease is before deciding if you can take PREZISTA.
- Tell your doctor if you have **diabetes**. Anti-HIV medicines such as PREZISTA may increase sugar levels in the blood.
- Tell your doctor immediately if you notice any **symptoms of infection**.

- In some patients with advanced HIV and a history of opportunistic infection, signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started.
- Tell your doctor if you **notice changes in body fat**. Redistribution, accumulation or loss of body fat may occur in patients receiving a combination of antiretroviral medicines.
- Tell your doctor if you have **haemophilia (bleeding disease)**. Anti-HIV medicines, such as PREZISTA, may increase the risk of bleeding.
- Tell your doctor if you are allergic to sulpha medicines.

Taking PREZISTA with food and drink

PREZISTA must be taken together with food.

Pregnancy and breastfeeding

Always tell your healthcare provider if you are taking any other medicine.

If you are pregnant or breastfeeding your baby while taking PREZISTA 600 mg please consult your healthcare provider for advice.

You must not take PREZISTA during pregnancy and breastfeeding.

Driving and using machinery

Do not operate machines or drive if you feel dizzy after taking PREZISTA.

Taking other medicines with PREZISTA

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of PREZISTA with these medicines may cause undesirable interactions.

Please consult your doctor, pharmacist or other healthcare provider, for advice.

There are some medicines that you must not combine with PREZISTA. These are mentioned above under the heading “Do not take PREZISTA with any of the following medicines”.

Tell your doctor if you take any other anti-HIV medicines. PREZISTA can be combined with some other anti-HIV medicines, while other combinations are not recommended.

Tell your doctor if you are taking any of the following medicines:

- medicines to treat some infections such as tuberculosis (*rifampicin*).
- products that contain St. John’s Wort (*Hypericum perforatum*).
- medicines to prevent seizures (*phenobarbital, phenytoin, carbamazepine*).
- steroids (*dexamethasone*).
- medicines for heart disease or high blood pressure (*amiodarone, bepridil, felodipine, lignocaine, nifedipine, nicardipine, quinidine, digoxin and bosentan*).
- medicines used to reduce clotting of the blood (*warfarin*).
- hormonal contraceptives. PREZISTA might reduce the effectiveness of hormonal contraceptives. You must combine hormonal contraceptives with other birth control methods such as a condom.
- medicines to lower cholesterol levels (e.g. *simvastatin, lovastatin, pravastatin*).
- medicines for your immune system (*ciclosporin, tacrolimus, sirolimus*). Your doctor might want to do some additional tests.
- medicines to control asthma (*fluticasone propionate and salmeterol*).
- medicines against fungal infection (*ketoconazole, itraconazole, voriconazole*).
- medicines against bacterial infections (*rifabutin*).

- medicines for erectile dysfunction (*sildenafil, vardenafil, tadalafil*).
- antibiotics (*clarithromycin*).
- medicines to treat depression and anxiety (*paroxetine, sertraline, trazodone*).
- *methadone* (pain killer).
- medicines to treat gout (*colchicine*).

HOW TO TAKE PREZISTA

Do not share medicines prescribed for you with any other person.

Always take PREZISTA exactly as your doctor has told you. You must check with your doctor or pharmacist if you are not sure.

The usual dose of PREZISTA is one tablet twice daily.

This is one tablet (600 milligram) in the morning and one tablet (600 milligram) in the evening.

You must take PREZISTA every day and always in combination with 100 milligram of ritonavir and with food in the morning and in the evening, at approximately the same time of day.

PREZISTA cannot work properly without ritonavir and food. You must eat a meal or a snack 30 minutes before you take your PREZISTA and ritonavir. The type of food is not important.

Swallow the tablet with a drink such as water, milk or any other nutritional drink.

Even if you feel better, do not stop taking PREZISTA without talking to your doctor.

Make sure that you always have enough PREZISTA and ritonavir tablets available so that you do not run out, for example, in case you cannot return home, need to travel or stay in a hospital.

Removing the child-resistant cap



The plastic bottle comes with a child-resistant cap and should be opened as follows:

- Push the plastic screw cap down while turning it counter clockwise.
- Remove the unscrewed cap.

If you have the impression that the effect of PREZISTA is too strong or too weak, tell your doctor or pharmacist.

If you take more PREZISTA than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take PREZISTA

If you notice **within 6 hours**, you must take your tablet immediately. Always take with ritonavir and food. If you notice **after 6 hours**, then take the next dose as usual. Do not take a double dose to make up for a forgotten dose.

POSSIBLE SIDE EFFECTS

PREZISTA can cause side effects.

Not all side effects reported for PREZISTA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PREZISTA, please consult your healthcare provider for advice.

The most common side effects are:

- nausea, vomiting
- headache
- stomach pain, diarrhoea, constipation, flatulence, rash and itchiness
- tiredness, loss of strength and energy, enlargement of breasts.

In some patients, PREZISTA has been reported to cause a severe or life-threatening rash. Contact your doctor if you develop a rash. Your doctor will advise you whether your symptoms can be managed on therapy or whether PREZISTA should be stopped. PREZISTA should not be taken if you suffer from liver problems.

Other side effects include:

- raised blood sugar and worsening of diabetes.
- muscle pain, tenderness or weakness. On rare occasions, these muscle disorders have been serious.
- changes in body shape due to fat redistribution. These may include loss of fat from legs, arms and face, increased fat in the abdomen (belly) and other internal organs, breast enlargement and fatty lumps on the back of the neck (buffalo hump).

The cause and long-term health effects of these conditions are not known at this time.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or

pharmacist.

STORING AND DISPOSING OF PREZISTA

PREZISTA should be stored at or below 30 °C (in a lockable cupboard).

Do not store in a bathroom.

Protect from light.

Keep in original packaging until required for use.

Keep the bottle tightly closed.

Do not use PREZISTA after the expiry date, which is stated on the box and on the bottle after the letters EXP. The expiry date refers to the last day of the month.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF PREZISTA

PREZISTA film-coated tablets are provided in white, high-density polyethylene (HDPE) plastic bottles containing 60 tablets fitted with yellow polypropylene (PP) child resistant closures, lined with a silver aluminium induction seal. Bottles are packed into an outer cardboard carton together with a leaflet.

IDENTIFICATION OF PREZISTA

PREZISTA film-coated tablets are white oval-shaped, debossed with 600MG on one side and TMC on the other side.

REGISTRATION NUMBER

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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