PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

PREZISTA® 400 mg

Film-coated tablet

Read all of this 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 of PREZISTA 400 mg contains 400 mg of darunavir (as darunavir ethanolate).

The other ingredients are colloidal silicon dioxide, crospovidone, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, FD&C Yellow #6 Aluminium Lake, talc, titanium dioxide.

Sugar free

WHAT PREZISTA IS USED FOR

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

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 by 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) (*phenobarbitone or phenytoin*)
- medicines to treat allergy symptoms (*astemizole*)
- medicines to treat tuberculosis (*rifampicin, rifabutin*)
- medicines to treat high blood pressure as a result of problems with your lungs (*sildenafil, bosentan*)
- medicines to treat gout if you have liver or kidney problems (*colchicine*)
- medicines to treat prostate problems (*alfuzosin*)
- medicines to treat migraine and headaches (*dihydroergotamine, ergonovine, ergotamine, methylergonovine*)
- medicines to treat some stomach conditions (*cisapride*)
- medicines to treat hepatitis C virus (*boceprevir, telaprevir*)

- herbal products containing St John's wort (e.g. for depression)
- medicines to treat high cholesterol (*lovastatin and 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, voriconazole*)
- medicines to treat narcotic dependence (*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 experience joint aches and pain, joint stiffness or difficulty in movement.
- 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

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine. You must not take PREZISTA during pregnancy and breastfeeding.

The safe use of PREZISTA in pregnancy and during breastfeeding has not been established.

Driving and using machinery

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

Taking other medicines with PREZISTA

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines.)

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 take:

- medicines to prevent seizures (*carbamazepine*)
- steroids (*dexamethasone*)
- medicines for heart disease or high blood pressure (*amiodarone, bepridil, felodipine, lignocaine, nifedipine, nicardipine, quinidine, digoxin*)
- medicines used to reduce clotting of the blood (*warfarin*)
- oestrogen based hormonal contraceptives. PREZISTA might reduce the effectiveness of hormonal contraceptives. Therefore, alternative methods of non-hormonal contraception are recommended.
- medicines to lower cholesterol levels (*e.g. atorvastatin, pravastatin and rosuvastatin*). The risk of muscle tissue disorder might be increased. Atorvastatin, pravastatin or rosuvastatin, at a reduced starting dose, could be used.
- medicines for your immune system (*ciclosporin, tacrolimus, sirolimus*). Your doctor might want to do some additional tests.
- medicines to control asthma (*fluticasone and salmeterol*)
- medicines for erectile dysfunction (*sildenafil, vardenafil, tadalafil*)
- antibiotics (*clarithromycin*)
- medicines to treat depression and anxiety (*paroxetine, sertraline*)
- medicines to treat narcotic dependence (*methadone)*
- medicines to treat gout or familial Mediterranean fever (*colchicine*)
- a combination medicine to treat malaria *(artemether/lumefantrine*).

HOW TO TAKE PREZISTA

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

The usual dose of PREZISTA 400 mg is two tablets once daily.

You must take PREZISTA every day and always in combination with 100 mg of ritonavir and with food at approximately the same time of day. PREZISTA cannot work properly without ritonavir and food.

You must eat a meal or 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 don't 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 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 12 hours**, you must take your tablet immediately. Always take with ritonavir and food. If you notice **after 12 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.

If any of the following happens, stop taking PREZISTA and tell your doctor immediately or go to the casualty department of the nearest hospital:

- severe rash with blisters
- rash or itching with swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.

These are all very serious effects. If you have them, you may have had a serious allergic reaction to PREZISTA. You may need urgent medical attention.

Speak to your doctor immediately or go to the casualty department of your nearest hospital if you experience any of the following side effects:

- symptoms of infection or inflammation after the start of treatment (immune reconstitution inflammatory syndrome)
- inflammation of the liver or pancreas (symptoms may include abdominal pain, nausea and vomiting)
- diabetes

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you experience any of the side effects listed below:

The most frequent side effects are:

- headache
- vomiting, nausea
- diarrhoea, stomach pain
- rash
- high cholesterol and other fats in the blood
- high blood sugar

Less frequent side effects are:

- changes in body fats (fat redistribution)
- loss of appetite
- abdominal swelling, indigestion, flatulence
- itching
- muscle pain
- loss of strength and energy, tiredness
- increase in pancreatic enzymes

PREZISTA may change some values of your blood chemistry. These can be seen in the results of blood tests. Your doctor will explain these to you.

In some patients, PREZISTA has been reported to cause a severe or life-threatening rash. In patients taking PREZISTA and raltegravir, rashes (generally mild or moderate) may occur more frequently than in patients taking either medicine separately. 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.

Some side effects are typical for anti-HIV medicines in the same family as PREZISTA. These 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).
- joint aches and pains, joint stiffness or difficulty in movement.

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

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 doctor, pharmacist or other healthcare professional for advice.

STORING AND DISPOSING OF PREZISTA

Store at or below 30 °C.

Keep the bottle tightly closed.

Keep in original packaging until required for use.

Do not store in a bathrooms.

Do not use after the expiry date stated on the label.

Return all unused medicines to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF PREZISTA

60 tablets are packed in a white, high-density polyethylene bottle and sealed with a white, polypropylene child resistant closure, lined with an aluminium induction seal.

IDENTIFICATION OF PREZISTA

Light orange oval shaped, film-coated tablet, debossed with “TMC” and “400MG” on opposite sides.

REGISTRATION NUMBER

47/20.2.8/1173

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

JANSSEN PHARMACEUTICA (Pty) Ltd

2 Medical street

Halfway House

Midrand

1685

Tel: +27115187000

www.janssen.com

DATE OF PUBLICATION

Date of registration: 2 June 2017

Date of the most recent amendment to the patient information leaflet as approved by the Authority:

2 June 2017