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## Darunavir for HIV (Prezista)

Clinical Author's Note (Michael Stewart) 18/07/2018: new data show that women who are pregnant and are taking darunavir have lower blood levels of the medicine compared to other patients. This means there may be a risk of the treatment not working properly and of HIV being passed on to the unborn child. Women who are pregnant or may become pregnant should not take darunavir and should speak with their doctor about other treatments. For more information please refer to the MHRA advice for healthcare professionals.

Darunavir slows the progress of HIV infection, but it is not a cure. It is one of a number of medicines that you will need to take regularly.

Take darunavir with a meal.

Darunavir has been associated with some side-effects. Your doctor will discuss these with you before you start treatment.

#### **About darunavir**

Type of medicine	A protease inhibitor (PI) antiretroviral medicine
Used for	Human immunodeficiency virus (HIV) infection in adults and in children over 3 years of age
Also called	Prezista®  Combination brands: Rezolsta® (darunavir with cobicistat);  Symtuza® (darunavir, cobicistat, emtricitabine and tenofovir)
Available as	Tablets and oral liquid medicine

Darunavir is an antiretroviral medicine. It is prescribed for human immunodeficiency virus (HIV) infection. It slows the progress of HIV infection, but it is not a cure. HIV destroys cells in the body, called CD4 T cells. These cells are a type of white blood cell and are important because they are involved in protecting your body from infection. If left untreated, the HIV infection weakens your immune system so that your body cannot defend itself against bacteria, viruses and other germs. Darunavir slows down the progress of HIV infection by reducing the amount of virus in your body. It does this by stopping the production of a protein that the virus needs to copy (replicate) itself.

Darunavir will be prescribed for you by a doctor who is a specialist. It belongs to a group of antiretroviral medicines known as protease inhibitors (PIs). It is given alongside a number of other antiretroviral medicines, as part of a combination therapy. Taking three or more antiretroviral medicines at the same time is more effective than taking one alone. Taking a combination of different medicines also reduces the risk that the virus will become resistant to any individual medicine. One brand of darunavir called Rezolsta® also contains a medicine called cobicistat. Cobicistat boosts the effect of darunavir. Not all of the information in this document may apply to the combination brand – please refer to the manufacturer's printed information leaflet from inside the pack.

It is vital to take your antiretroviral medicines exactly as prescribed to maintain success and to help to prevent the virus from becoming resistant to the medicines. These medicines are usually taken for life.

#### Before taking darunavir

Some medicines are not suitable for people with certain conditions, and sometimes a medicine can only be used if extra care is taken. For these reasons, before you start taking darunavir it is important that your doctor knows:

- If you are pregnant, trying for a baby or breastfeeding.
- If you have diabetes (diabetes mellitus).
- If you have liver inflammation (called hepatitis), or any other liver problem.
- If you have either haemophilia or porphyria, which are both rare inherited blood disorders.
- If you are taking any other medicines. This includes any medicines which are available to buy without a prescription, as well as herbal and complementary medicines.
- If you have ever had an allergic reaction to a medicine. This is particularly important if you know you are allergic to a medicine known as a sulfonamide.

#### How to take darunavir

- Before you start the treatment, read the manufacturer's printed information leaflet from inside the pack. It will give you more information about darunavir, and it will also provide you with a full list of the side-effects which you could experience from taking it.
- Take darunavir exactly as your doctor tells you to. You will be asked to take either one or two doses daily, at the same time as a booster medicine (either ritonavir or cobicistat).
- There are several strengths of darunavir tablets available your doctor will tell you which is right for you (or your child). It is important that you take darunavir at a mealtime (or within 30 minutes of eating a meal) as this will help your body to absorb the medicine.

- Try to take darunavir at the same time(s) of day each day, as this will help you to remember to take it regularly.
- If you forget to take your dose, take it with something to eat as soon as you remember unless:
  - You usually take darunavir twice a day and you are more than 6 hours late; in which case do not take the missed dose but do take your next dose when it is due.
  - You usually take darunavir once a day and you are more than 12 hours late; in which case do not take the missed dose but do take your next dose when it is due.

# Instructions for using the dosing syringe with Prezista® Oral Suspension

- 1. Shake the bottle well.
- 2. Remove the bottle cap.
- 3. Make sure the plunger of the syringe is pushed in fully, then insert the syringe into the bottle.
- 4. Gently pull out the plunger of the syringe so that the medicine fills the syringe to the mark which corresponds to your dose.
- 5. Put the tip of the syringe into your (or your child's) mouth, and gently push the plunger so that the medicine is released.
- 6. Replace the bottle cap. Wash the syringe with water after each use.

### Getting the most from your treatment

- Keep your regular appointments with your doctor so that your progress can be monitored. You will need to have regular blood tests while you are taking this medicine, to make sure your liver stays healthy.
- It is important that you continue to take darunavir and your other antiretroviral treatment regularly. This will help to prevent the HIV from becoming resistant to the medicines you are taking. Even if you miss only a small number of doses, the virus can become resistant to treatment.

- If you develop any infection soon after you start this treatment, let your doctor know. As a result of taking darunavir, your immune system may start fighting an infection which was present before you started the treatment, but which you may not have been aware of.
- Follow carefully any advice your doctor gives to you about making lifestyle changes to reduce any risk of damage to your heart and blood vessels. These can include stopping smoking, eating healthily and taking regular exercise.
- Some people taking antiretroviral medicines develop changes to the way body fat is distributed in the body. This can result in changes to body image. Your doctor will discuss the possibility of this with you.
- Although treatment with antiretroviral medicines may reduce the risk of you passing HIV to others through sexual contact, it does not stop it. It is important that you use condoms.
- Being pregnant whilst taking darunavir can lead to lower blood levels
  of the medicine. This may mean your treatment becomes less
  effective than it should be. If you are pregnant, or planning to
  become pregnant, speak with your doctor for advice on alternative
  treatments.
- It is not uncommon for people with HIV to feel low or even depressed, especially soon after the diagnosis has been made and treatment has been started. If you have any feelings of depression, or any distressing thoughts about harming yourself then you should speak with your doctor straightaway.
- Some people who have taken antiretroviral medicines (particularly over a long time) have developed a condition called osteonecrosis.
   This is a bone disease where bone tissue dies because there is a reduced blood supply to it. It leads to joint pains and stiffness, and can cause difficulties in movement. If you notice any of these symptoms, speak with your doctor.
- If you buy any medicines, check with a pharmacist that they are suitable to take with darunavir and your other medicines. This is because some medicines interfere with darunavir and either stop it from working properly or increase the risk of side-effects. In particular, do not take the herbal remedy St John's wort.

- If you have diabetes you may need to check your blood sugar (glucose) more frequently, as this medicine can affect the levels of sugar in your blood. Your doctor will advise you about this.
- If you are having an operation or dental treatment, tell the person carrying out the treatment which medicines you are taking.
- Treatment for HIV is usually lifelong. Continue to take darunavir regularly for as long as your doctor tells you to, even if you feel well.
   This is to keep your immune system healthy.

## Can darunavir cause problems?

Along with their useful effects, most medicines can cause unwanted side-effects although not everyone experiences them. The table below contains some of the most common ones associated with darunavir. You will find a full list in the manufacturer's information leaflet supplied with your medicine. The unwanted effects often improve as your body adjusts to the new medicine, but speak with your doctor or pharmacist if any of the following continue or become troublesome.

Very common darunavir side-effects (these affect more than 1 in 10 people)	What can I do if I experience this?	
Diarrhoea	Drink plenty of water to replace lost fluids	
Common darunavir side-effects (these affect fewer than 1 in 10 people)	What can I do if I experience this?	
Rash	Speak with your doctor about this (see below)	
Feeling sick (nausea) or being sick (vomiting), tummy (abdominal) pain, feeling bloated, wind, indigestion	Stick to simple meals - avoid fatty or spicy food	
Headache	Drink plenty of water and ask a pharmacist to recommend a suitable painkiller. If the headaches continue, let your doctor know	
Feeling tired, sleepy or dizzy	Do not drive and do not use tools or machines while affected	
Body fat changes, difficulty sleeping, tiredness, tingling or numb feelings in your hands or feet	Discuss these with your doctor if troublesome	
Changes to the results of some blood tests	Your doctor will check for this	

**Important**: although it is common for people taking darunavir to develop a skin rash during the first few weeks of treatment, a severe rash with blisters may be a sign of a more serious allergic-type reaction. Let your doctor know **straightaway** if you develop the following:

 Severe blistering rash, high temperature, muscle and joint aches or pains, feeling generally unwell, mouth ulcers, and conjunctivitis.

If you experience any other symptoms which you think may be due to the medicine, speak with your doctor or pharmacist for further advice.

#### How to store darunavir

- Keep all medicines out of the reach and sight of children.
- Store in a cool, dry place, away from direct heat and light.

## Important information about all medicines

Never take more than the prescribed dose. If you suspect that you or someone else might have taken an overdose of this medicine, go to the accident and emergency department of your local hospital at once. Take the container with you, even if it is empty.

This medicine is for you. Never give it to other people even if their condition appears to be the same as yours.

Do not keep out-of-date or unwanted medicines. Take them to your local pharmacy which will dispose of them for you.

If you have any questions about this medicine ask your pharmacist.

If you experience side effects, you can report them online through the Yellow Card website.

#### **Further reading**

- Manufacturer's PIL, Prezista® 100 mg/ml oral suspension; Janssen-Cilag Ltd,The electronic Medicines Compendium. Dated January 2021.
- Manufacturer's PIL, Prezista® 800 mg film-coated tablets; Janssen-Cilag Ltd,The electronic Medicines Compendium. Dated January 2021.
- Medicines Complete BNF 87th Edition; British Medical Association and Royal Pharmaceutical Society of Great Britain, London.

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