



Package leaflet: Information for the user

REZOLSTA® 675 mg/150 mg film-coated tablets

darunavir/cobicistat

Read all of this leaflet carefully before you (or your child) start taking this medicine because it contains important information for you.

- Keep this leaflet. You or your child may need to read it again.
- If you or your child have any further questions, ask your or your child's doctor, pharmacist or nurse.
- This medicine has been prescribed for you or your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours (or your child's).
- If you or your child get any side effects, talk to your (or your child's) doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- The information in this leaflet is for you or your child - but in this leaflet we usually just say you.

What is in this leaflet

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1 What REZOLSTA is and what it is used for

What is REZOLSTA?

REZOLSTA contains the active substances darunavir and cobicistat. Darunavir belongs to a group of HIV medicines called 'protease inhibitors' which work by reducing the amount of HIV in your body to a very low level. It is given with cobicistat, which increases the amount of darunavir in your blood. Treatment with REZOLSTA will improve your immune system (your body's natural defences) and reduce the risk of developing illnesses linked to HIV infection, but REZOLSTA is not a cure for HIV infection.

What it is used for?

REZOLSTA 675 mg/150 mg (darunavir/cobicistat) is used to treat children aged 6 years and older who weigh at least 25 kilograms to less than 40 kilograms and who are infected by HIV (see How to take REZOLSTA in this leaflet).

REZOLSTA must be taken in combination with other HIV medicines. Your doctor will discuss with you which combination of medicines is best for you.

2 What you need to know before you take REZOLSTA

Do not take REZOLSTA

- if you are **allergic** to darunavir, cobicistat or any of the other ingredients of this medicine (listed in section 6).
- if you have **severe liver problems**. Ask your doctor if you are unsure about the severity of your liver disease. Some additional tests might be necessary.

Tell your doctor about **all** medicines you take including medicines taken orally, inhaled, injected or applied to the skin.

Do not combine REZOLSTA with any of the following medicines

If you are taking any of these, ask your doctor about switching to another medicine.

Medicine	Purpose of the medicine
<i>Alfuzosin</i>	to treat enlarged prostate
<i>Amiodarone, bepridil, dronedarone, ivabradine, quinidine, ranolazine</i>	to treat certain heart disorders e.g. abnormal heart beat
<i>Carbamazepine, phenobarbital and phenytoin</i>	to prevent seizures
<i>Astemizole or terfenadine</i>	to treat allergy symptoms
<i>Colchicine</i> (if you have kidney/liver problems)	to treat gout or familial Mediterranean fever
<i>The combination product lopinavir/ritonavir</i>	anti-HIV medicine
<i>Rifampicin</i>	to treat some infections such as tuberculosis
<i>Lurasidone, pimozone, quetiapine or sertindole</i>	to treat psychiatric conditions
<i>Ergot alkaloids</i> like <i>ergotamine, dihydroergotamine, ergometrine</i> and <i>methylergonovine</i>	to treat migraine headaches
<i>Cisapride</i>	to treat some stomach conditions
<i>St John's Wort (Hypericum perforatum)</i>	a herbal product used for depression
<i>Elbasvir/grazoprevir</i>	to treat hepatitis C infection
<i>Lovastatin, simvastatin, and lomitapide</i>	to lower cholesterol levels
<i>Triazolam</i> or <i>oral</i> (taken by mouth) <i>midazolam</i>	to help you sleep and/or relieve anxiety
<i>Sildenafil</i>	to treat a heart and lung disorder called pulmonary arterial hypertension. There are other uses for sildenafil. Please see section 'Other medicines and REZOLSTA'.
<i>Avanafil</i>	to treat erectile dysfunction
<i>Ticagrelor</i>	to help stop the clumping of platelets in the treatment of patients with a history of a heart attack
<i>Naloxegol</i>	to treat opioid induced constipation
<i>Dapoxetine</i>	to treat premature ejaculation
<i>Domperidone</i>	to treat nausea and vomiting

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking REZOLSTA.

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

People taking REZOLSTA may develop a skin rash. Infrequently a rash may become severe or potentially life-threatening. Please contact your doctor whenever you develop a rash.

In patients taking REZOLSTA and raltegravir (for HIV infection), rashes (generally mild or moderate) may occur more frequently than in patients taking either medicine separately.

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, including hepatitis B or C infection. Your doctor may evaluate how severe your liver disease is before deciding if you can take REZOLSTA.
- Tell your doctor if you have had **problems with your kidneys**. Your doctor will carefully consider whether to treat you with REZOLSTA.
- Tell your doctor if you have **diabetes**. REZOLSTA might increase sugar levels in the blood.
- Tell your doctor immediately if you notice any **symptoms of infection** (for example enlarged lymph nodes and fever). In some patients with advanced HIV infection and a history of unusual infections due to a weakened immune system (opportunistic infection), signs and symptoms of inflammation from previous infections may occur soon after HIV treatment is started. It is believed that these symptoms are due to an improvement in the body's immune response, enabling the body to fight infections that may have been present with no obvious symptoms.
- In addition to the opportunistic infections, **autoimmune disorders** (a condition that occurs when the immune system attacks healthy body tissue) may also occur after you start taking medicines for the treatment of your HIV infection. Autoimmune disorders may occur many months after the start of treatment. If you notice any symptoms of infection or other symptoms such as muscle weakness, weakness beginning in the hands and feet and moving up towards the trunk of the body, palpitations, tremor or hyperactivity, please inform your doctor immediately so you can be given the necessary treatment.
- Tell your doctor if you have **haemophilia**. REZOLSTA might increase the risk of bleeding.
- Tell your doctor if you are **allergic to sulphonamides** (e.g. used to treat certain infections).
- Tell your doctor if you notice any **musculoskeletal problems**. Some patients taking combination antiretroviral therapy may develop a bone disease called osteonecrosis (death of bone tissue caused by loss of blood supply to the bone). This may be more likely with long-term HIV treatment, more severe damage to the immune system, overweight, or the use of alcohol or other medicines called corticosteroids. Signs of osteonecrosis are joint stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty in movement. If you notice any of these symptoms please inform your doctor.

The effects of other medicines might be influenced if you take REZOLSTA and your doctor might want to do some additional blood tests. Tell your doctor if you take:

- *Amlodipine, carvedilol, diltiazem, disopyramide, felodipine, flecainide, lidocaine, metoprolol, mexiletine, nicardipine, nifedipine, propafenone, timolol, verapamil* (for heart disease) as the therapeutic effect or side effects of these medicines may be increased.
- *Apixaban, dabigatran etexilate, edoxaban, rivaroxaban, warfarin, clopidogrel* (to reduce clotting of the blood) as their therapeutic effect or side effects may be altered.
- *Clonazepam* (to prevent seizures).
- Oestrogen-based hormonal contraceptives and hormone replacement therapy. REZOLSTA might reduce its effectiveness. When used for birth control, alternative methods of non-hormonal contraception are recommended.
- *Ethinylestradiol/drospirenone*. REZOLSTA might increase the risk for elevated potassium levels by drospirenone.
- *Atorvastatin, fluvastatin, pitavastatin, pravastatin, rosuvastatin* (to lower cholesterol levels). The risk of muscle damage might be increased. Your doctor will evaluate which cholesterol lowering regimen is best for your specific situation.
- *Ciclosporin, everolimus, tacrolimus, sirolimus* (for dampening down your immune system) as the therapeutic effect or side effects of these medicines might be increased.
- *Corticosteroids including betamethasone, budesonide, fluticasone, mometasone, prednisone, triamcinolone*. These medicines are used to treat allergies, asthma, inflammatory bowel diseases, inflammatory conditions of the skin, eyes, joints and muscles and other inflammatory conditions. These medicines are generally taken orally, inhaled, injected or applied to the skin. If alternatives cannot be used, its use should only take place after medical evaluation and under close monitoring by your doctor for corticosteroid side effects.
- *Buprenorphine/naloxone, methadone* (medicines to treat opioid dependence)
- *Salmeterol* (medicine to treat asthma)
- *Artemether/lumefantrine* (a combination medicine to treat malaria)
- *Dasatinib, irinotecan, nilotinib, vinblastine, vincristine* (medicines to treat cancer)
- *Perphenazine, risperidone, thioridazine* (psychiatric medicines)
- *Clorazepate, diazepam, estazolam, flurazepam* (medicines to treat sleeping disorders or anxiety)
- *Sildenafil, tadalafil, vardenafil* (for erectile dysfunction or to treat a heart and lung disorder called pulmonary arterial hypertension)
- *Glecaprevir/pibrentasvir* (to treat hepatitis C infection)
- *Fesoterodine, solifenacin* (to treat urologic disorders).

Your doctor might want to do some additional blood tests and the dosage of other medicines might need to be changed since either their own or REZOLSTA's therapeutic effect or side effects may be influenced when combined. Tell your doctor if you take:

- *Dabigatran etexilate, edoxaban, warfarin* (to reduce clotting of the blood)
- *Alfentanil* (injectable, strong and short-acting, painkiller that is used for surgical procedures)
- *Digoxin* (to treat certain heart disorders)
- *Clarithromycin* (antibiotic)
- *Clotrimazole, fluconazole, itraconazole, isavuconazole, posaconazole* (against fungal infections). *Voriconazole* should only be taken after medical evaluation.
- *Rifabutin* (against bacterial infections)
- *Tadalafil, sildenafil, vardenafil* (for erectile dysfunction or high blood pressure in the pulmonary circulation)
- *Amitriptyline, desipramine, imipramine, nortriptyline, dapoxetine, sertraline, trazodone* (to treat depression and anxiety)
- *Maraviroc* (to treat HIV infection)
- *Colchicine* (to treat HIV infection)
- If you have renal and/or hepatic impairment see section '**Do not combine REZOLSTA with any of the following medicines**'.
- *Bosentan* (to treat high blood pressure in the pulmonary circulation)
- *Buspirone, clorazepate, diazepam, estazolam, flurazepam, zolpidem, midazolam when used as injection* (medicines to treat trouble with sleeping and/or anxiety)
- *Metformin* (to treat type 2 diabetes)
- *Fentanyl, oxycodone, tramadol* (to treat pain).

This is **not** a complete list of medicines. Tell your healthcare provider about **all** medicines that you are taking.

Children and adolescents

This medicine is not for use in children younger than 6 years of age, or weighing less than 25 kilograms.

REZOLSTA is also available as a 800 mg/150 mg tablet for adolescents weighing at least 40 kg (see separate Package Leaflet for REZOLSTA 800 mg/150 mg film-coated tablets).

Other medicines and REZOLSTA

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

There are some medicines that **you must not combine** with REZOLSTA. These are mentioned above under the heading '**Do not combine REZOLSTA with any of the following medicines**'.

REZOLSTA must not be used with another antiviral medicine that contains a booster or another antiviral that requires boosting. In some cases dosage of other medicines might need to be changed. Therefore, always tell your doctor if you take other anti-HIV medicines and follow your doctor's instruction carefully on which medicines can be combined.

The effects of REZOLSTA might be reduced if you take any of the following products. Tell your doctor if you take:

- *Bosentan* (to treat heart disease)
- *Dexamethasone* (injectable) (corticosteroid)
- *Defavirenz, etravirine, nevirapine* (to treat HIV infection)
- *Rifapentine, rifabutin* (to treat bacterial infections).

2 What you need to know before you take REZOLSTA (continued)

Pregnancy and breast-feeding

Tell your doctor immediately if you are pregnant or planning to become pregnant. Pregnant women should not take REZOLSTA.

Because of the potential for side effects in breast-fed infants, women should not breast-feed if they are receiving REZOLSTA.

Breast-feeding is not recommended in women living with HIV because HIV infection can be passed on to the baby in breast milk. If you are breast-feeding, or thinking about breast-feeding, you should discuss it with your doctor as soon as possible.

Driving and using machines

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

REZOLSTA contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3 How to take REZOLSTA

Always use this medicine exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

You must take REZOLSTA every day and always with food. REZOLSTA cannot work properly without food. You must eat a meal or a snack within 30 minutes prior to taking your REZOLSTA. The type of food is not important.

- Swallow the tablet whole with a drink such as water or milk. If you have difficulty swallowing REZOLSTA, tell your doctor. The scored tablet can be split by hand into 2 pieces. The score line is only there to help you break the tablet. After splitting the tablet, the entire dose (both pieces) should be swallowed right away to get the full dose.
- Take your other HIV medicines used in combination with REZOLSTA as recommended by your doctor.

Removing the child resistant cap



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

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

If you take more REZOLSTA than you should

Contact your doctor, pharmacist or nurse immediately.

If you forget to take REZOLSTA

If you notice **within 12 hours**, you must take the tablet immediately. Always take with food. If you notice **after 12 hours**, then skip the intake and take the next doses as usual. Do not take a double dose to make up for a forgotten dose.

If you vomit after taking REZOLSTA

If you vomit **within 4 hours** of taking the medicine, another dose of REZOLSTA should be taken with food as soon as possible. If you vomit **more than 4 hours** after taking the medicine, then you do not need to take another dose of REZOLSTA until the next regularly scheduled time.

Contact your doctor **if you are uncertain** about what to do if you miss a dose or vomit.

Do not stop taking REZOLSTA without talking to your doctor first

After therapy has started, it must not be stopped without instruction of the doctor.

Anti-HIV medicines may make you feel better. Even when you feel better, do not stop taking REZOLSTA. Talk to your doctor first.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4 Possible side effects

During HIV therapy there may be an increase in weight and in levels of blood lipids and glucose. This is partly linked to restored health and life style, and in the case of blood lipids sometimes to the HIV medicines themselves. Your doctor will test for these changes.

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor if you develop any of the following side effects

Liver problems that may occasionally be severe have been reported. Your doctor should do blood tests before you start REZOLSTA. If you have chronic hepatitis B or C infection, your doctor should check your blood tests more often because you have an increased chance of developing liver problems. Talk to your doctor about the signs and symptoms of liver problems. These may include yellowing of your skin or whites of your eyes, dark (tea coloured) urine, pale coloured stools (bowel movements), nausea, vomiting, loss of appetite, or pain, aching, or pain and discomfort on your right side below your ribs.

A common side effect of REZOLSTA is skin rash (more often when used in combination with raltegravir), itching. The rash is usually mild to moderate. A skin rash might also be a symptom of a rare severe situation. It is, therefore, important to talk to your doctor if you develop a rash. Your doctor will advise you how to deal with your symptoms or whether REZOLSTA must be stopped.

Other severe side effects, seen up to 1 patient in 10, were diabetes. Inflammation of the pancreas (pancreatitis) has been reported in up to 1 patient in 100.

Very common side effects (may affect more than 1 in 10 people)

- headache
- diarrhoea, nausea.

Common side effects (may affect up to 1 in 10 people)

- allergic reactions such as itching
- decreased appetite
- abnormal dreams
- vomiting, pain or swelling of the belly, indigestion, flatulence
- muscle pain
- tiredness
- abnormal blood test results such as some tests for your liver or kidney. Your doctor will explain these to you.
- weakness.

Uncommon side effects (may affect up to 1 in 100 people)

- symptoms of infection or of autoimmune disorders (immune reconstitution inflammatory syndrome)
- osteonecrosis (death of bone tissue caused by loss of blood supply to the bone)
- enlargement of breasts
- abnormal blood test results such as some tests for your pancreas, high level of sugar, abnormal levels of 'lipids' (fats). Your doctor will explain these to you.
- allergic reactions such as nettle rash (urticaria), severe swelling of the skin and other tissues (most often the lips or the eyes)
- severe rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals.

Rare side effects (may affect up to 1 in 1,000 people)

- a reaction called DRESS [severe rash, which may be accompanied by fever, fatigue, swelling of the face or lymph glands, increase of eosinophils (type of white blood cells), effects on liver, kidney or lung]
- darunavir crystals in the kidney causing kidney disease.

Side effects with unknown frequency: a rash may become severe or potentially life-threatening:

- rash with blisters and peeling skin over much of the body
- red rash covered with small pus-filled bumps that can spread over the body, sometimes with a fever.

Some side effects are typical for HIV medicines in the same family as REZOLSTA. These are:

- muscle pain, tenderness or weakness. On rare occasions, these muscle disorders have been serious.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Yellow Card Scheme at:

<https://yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store REZOLSTA

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and on the bottle after EXP. The expiry date refers to the last day of that month.

Do not use this medicine after 8 weeks of first opening the bottle.

REZOLSTA does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What REZOLSTA contains

- The active substances are darunavir and cobicistat. Each tablet contains 675 mg of darunavir (as ethanolate) and 150 mg cobicistat.
- The other ingredients are colloidal silicon dioxide, cellulose, (microcrystalline), croscarmellose sodium and magnesium stearate. The film-coating contains iron oxide yellow (E 172), iron oxide black (E 172), polyethylene glycol (macrogol), polyvinyl alcohol (partially hydrolysed), talc, and titanium dioxide (E 171).

What REZOLSTA looks like and contents of the pack

Green to dark green, oval-shaped scored film-coated tablet, mentioning 675 on one side, TG on the other side.

30 tablets in a plastic bottle.

Marketing Authorisation Holder

Janssen-Cilag Ltd., 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK

Manufacturer

Janssen Pharmaceutica NV, Turnhoutseweg 30, B-2340 Beerse, Belgium

For information in large print, tape, CD or Braille, telephone 0800 7318450

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