

SYMTUZA® 800/150/200/10 Tablets

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using SYMTUZA?

SYMTUZA contains four active ingredients darunavir, cobicistat, emtricitabine and tenofovir alafenamide which works together to treat adults and adolescents 12 years of age and older who weigh at least 40 kg, who are infected by HIV (Human Immunodeficiency Virus).

For more information, see Section [1. Why am I using SYMTUZA?](#) in the full CMI.

2. What should I know before I use SYMTUZA?

Do not use if you have ever had an allergic reaction to SYMTUZA or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use SYMTUZA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SYMTUZA and affect how it works. **Do not combine SYMTUZA with medicines listed in Section 2. What should I know before I use SYMTUZA?**

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use SYMTUZA?

- Always take this medicine exactly as your doctor has told you. You must check with your doctor if you are not sure.
- The usual dose of SYMTUZA is one tablet orally, once daily with food. SYMTUZA cannot work properly without food. Swallow the tablets with a drink such as water, milk, or any other nutritional drink.

More instructions can be found in Section [4. How do I use SYMTUZA?](#) in the full CMI.

5. What should I know while using SYMTUZA?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using SYMTUZA.• Tell your doctor if you notice any symptoms of an infection.• Be sure to keep all your doctor's appointments so that your progress can be checked.• If you are undergoing anaesthesia, tell your anaesthetist that you are taking SYMTUZA.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking SYMTUZA without talking to your doctor first, even if you feel better.• Avoid doing things that can spread HIV infection since SYMTUZA does not stop you from passing the HIV infection to others.
Driving or using machines	<ul style="list-style-type: none">• Do not operate machines or drive if you feel dizzy after taking SYMTUZA.
Looking after your medicine	<ul style="list-style-type: none">• Store below 30°C and in the original packaging to protect from moisture.• Keep it where children cannot reach it.

For more information, see Section [5. What should I know while using SYMTUZA?](#) in the full CMI.

6. Are there any side effects?

The most common side effects of SYMTUZA are headache, abdominal pain, diarrhoea, rash and fatigue.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

SYMTUZA® 800/150/200/10 Tablets

Active ingredient(s): Darunavir/cobicistat/emtricitabine/tenofovir alafenamide

Consumer Medicine Information (CMI)

This leaflet provides important information about using SYMTUZA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using SYMTUZA.**

Where to find information in this leaflet:

1. [Why am I using SYMTUZA?](#)
2. [What should I know before I use SYMTUZA?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use SYMTUZA?](#)
5. [What should I know while using SYMTUZA?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using SYMTUZA?

SYMTUZA contains four active ingredients which work in combination for the treatment of HIV. These active ingredients are darunavir, cobicistat, emtricitabine and tenofovir alafenamide. Darunavir, emtricitabine and tenofovir alafenamide are called antiretroviral medicines. Darunavir is medicine known as a protease inhibitor. Emtricitabine is a medicine known as a nucleoside reverse transcriptase inhibitor. Tenofovir alafenamide is a medicine known as a nucleotide reverse transcriptase inhibitor. Each of these three active ingredients work to reduce the amount of HIV in your body.

Cobicistat is a type of medicine called a pharmacokinetic enhancer (or "booster"). Cobicistat helps to increase the levels of darunavir in your body.

Reducing the amount of HIV in your blood improves your immune system and reduces the risk of developing illnesses as a result of HIV infection.

SYMTUZA is a single tablet regimen used to treat adults and adolescents 12 years of age and older who weigh at least 40 kg, who are infected by HIV (Human Immunodeficiency Virus).

2. What should I know before I use SYMTUZA?

Warnings

Do not use SYMTUZA if:

- you are allergic to darunavir, cobicistat, emtricitabine and tenofovir alafenamide, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- Do not combine SYMTUZA with any of the following medicines:
 - o alfuzosin (to treat an enlarged prostate)

- o astemizole or terfenadine (to treat allergy symptoms)
- o amiodarone, bepridil, disopyramide, dronedarone, flecainide, systemic lidocaine, mexiletine, propafenone, quinidine (to treat irregular heartbeats)
- o ivabradine or ranolazine (to treat heart disease)
- o apixaban (used to reduce blood clotting)
- o cisapride (to treat some stomach conditions)
- o colchicine (to treat gout) if you have renal/hepatic impairment
- o lovastatin, simvastatin or lomitapide (to lower cholesterol levels)
- o lurasidone or pimozide (to treat psychiatric conditions)
- o midazolam or triazolam (to treat trouble with sleeping and/or anxiety)
- o carbamazepine, phenobarbital, phenytoin (medicines to prevent seizures)
- o ergot alkaloids i.e. dihydroergotamine, ergonovine, ergotamine, methylergonovine (to treat migraine and headaches)
- o sildenafil (to treat pulmonary arterial hypertension)
- o rifampin (to treat some infections such as tuberculosis)
- o elbasvir/grazoprevir (to treat hepatitis C)
- o products that contain St John's wort (*Hypericum perforatum*) which is a herbal supplement used for depression and anxiety
- o naloxegol (to treat constipation caused by taking opioids)
- o dapoxetine (to treat premature ejaculation)

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

Serious problems can happen if you take any of the medicines listed above with SYMTUZA.

In addition, you should also not take SYMTUZA with medicines that contain tenofovir disoproxil fumarate, lamivudine, or adefovir dipivoxil, or any anti-HIV medicines that have to be taken with ritonavir or cobicistat boosters.

This is **not** a complete list of medicines. Therefore, tell your doctor about **all** medicines you take.

There are other medicines that you need to be careful of when taking SYMTUZA (see Section [3. What if I am taking other medicines?](#))

Check with your doctor if you:

- have or have had any other medical conditions, especially the following:
 - o **Problems with your liver, including hepatitis B and C.** Your doctor may need to evaluate how severe your liver disease is before deciding if you can take SYMTUZA. If you have hepatitis B, liver problems may become worse after you stop

taking SYMTUZA. It is important not to stop taking SYMTUZA without talking to your doctor first.

- o **Diabetes.** SYMTUZA, like some other anti-HIV medicines, might increase sugar levels in the blood.
 - o **Problems with your kidney.** Your doctor should do blood and urine test before starting and during treatment with SYMTUZA. Your doctor may tell you to stop taking SYMTUZA if you develop new or worse kidney problems.
 - o Are allergic to foods, dyes, preservatives, sulfa medicines (sulphonamides) or any other medicines.
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Tell your doctor immediately if you are pregnant or intend to become pregnant.

Tell your doctor immediately if you are breastfeeding or intend to breastfeed.

Do not take SYMTUZA if you are pregnant or breastfeeding.

It is recommended that HIV infected women should not breastfeed their infants because of the possibility of your baby becoming infected with HIV through your breast milk and because of the unknown effects of the medicine on your baby. If you are a woman who has or will have a baby, talk with your doctor about the best way to feed your baby.

Use in Children and adolescents:

SYMTUZA should not be given to children younger than 12 years of age or weighing less than 40 kg.

Take special care with SYMTUZA:

- SYMTUZA is not a cure for HIV infection.
- Talk to your doctor about appropriate precautions to lower the chance of spreading HIV to others.
- People taking SYMTUZA can still develop infections or other illnesses associated with HIV. You should continue to keep in regular contact with your doctor and to monitor your health while taking SYMTUZA.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

There are some medicines that you **must not** combine with SYMTUZA. These are mentioned above under the subsection '[Do not use SYMTUZA if](#)'.

Tell your doctor if you take other anti-HIV medicines. SYMTUZA can be combined with some other anti-HIV

medicines while other combinations are not recommended or should not be used.

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

- medicines to treat hepatitis C (boceprevir, glecaprevir/pibrentasvir)
- medicines to prevent seizures (oxcarbazepine)
- corticosteroids (dexamethasone)
- medicines to treat excessive sleepiness (armodafinil, modafinil)
- medicines to treat some infections such as tuberculosis (rifabutin, rifapentine)

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

- medicines for heart disease (amlodipine, diltiazem, felodipine, nifedipine, nicardipine, tadalafil, verapamil)
- medicines used to reduce clotting of the blood (dabigatran etexilate, edoxaban, rivaroxaban, warfarin) or to prevent blood clots (ticagrelor, clopidogrel)
- oestrogen-based hormonal contraceptives. SYMTUZA might reduce the effectiveness of hormonal contraceptives and/or increase their side effects. Therefore, alternative methods of non-hormonal contraception are recommended. If you take a contraceptive containing drospirenone your potassium levels might become elevated.
- medicines for your immune system (cyclosporin, everolimus, tacrolimus, sirolimus). Your doctor might want to do some additional tests.
- medicines to control asthma (budesonide, fluticasone, salmeterol).
- medicines to treat gout (colchicine). If you have renal/hepatic impairment, do not take colchicine with SYMTUZA.
- medicines to treat malaria (artemether/lumefantrine)
- medicines to treat cancer (dasatinib, everolimus, irinotecan, nilotinib, vinblastine, vincristine)
- medicines to prevent seizures (clonazepam)
- medicines to treat psychiatric conditions (perphenazine, quetiapine, risperidone, thioridazine)
- medicines against bacterial infections (erythromycin and telithromycin)
- corticosteroids (betamethasone, mometasone, prednisone, triamcinolone)
- medicines to treat pain (fentanyl, oxycodone, tramadol)
- medicines to treat urinary disorders (fesoterodine, solifenacin)
- medicines to treat nausea and vomiting (domperidone)

The dosage of other medicines might need to be changed and your doctor might do some additional blood tests. Tell your doctor if you take:

- medicines to treat certain heart disorders (digoxin, carvedilol, metoprolol, timolol, bosentan)

- medicines to treat fungal infections (clotrimazole, fluconazole, isavuconazole, itraconazole, ketoconazole, posaconazole, voriconazole)
- medicines against bacterial infections (clarithromycin)
- medicines for erectile dysfunction (avanafil, vardenafil, sildenafil, tadalafil)
- medicines to lower cholesterol levels (atorvastatin, pitavastatin, pravastatin, rosuvastatin).
- medicines to treat depression and anxiety (amitriptyline, desipramine, imipramine, nortriptyline, paroxetine, sertraline, trazodone)
- medicines to treat narcotic dependence (buprenorphine/naloxone, methadone)
- sedatives (buspirone, clorazepate, diazepam, estazolam, flurazepam, zolpidem)

This is **not** a complete list of medicines. Therefore, tell your doctor about **all** medicines you take.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SYMTUZA.

4. How do I use SYMTUZA?

How much to take

- The usual dose of SYMTUZA is one tablet orally, once daily with food.
- Follow the instructions provided and use SYMTUZA until your doctor tells you to stop.
- Always use SYMTUZA exactly as your doctor has told you. You must check with your doctor if you are not sure.
- Make sure that you always have enough SYMTUZA available so that you don't run out. For example, in case you cannot return home, need to travel or stay in a hospital. This is very important because the amount of virus may start to increase if the medicine is stopped for even a short time.

When and how to take SYMTUZA

- **You must take SYMTUZA every day and always with food.** SYMTUZA cannot work properly without food.
- **You must eat a meal or a snack within 30 minutes prior to taking your SYMTUZA.** The type of food is not important.
- Even if you feel better, do not stop taking SYMTUZA without talking to your doctor.

How to take SYMTUZA

- Take SYMTUZA with food.
- Swallow the tablets with a drink such as water, milk, or any other nutritional drink.
- Take SYMTUZA at approximately the same time each day.
- If you are unable to swallow the whole tablet, tell your doctor. SYMTUZA may be split into two pieces using a tablet-cutter, and the entire dose should be taken with food immediately after splitting. Your doctor will determine whether SYMTUZA or its individual components are right for you.

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 forget to take SYMTUZA

- SYMTUZA should be taken regularly at the same time each day.
- If you notice within 12 hours, you must take the tablets 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 the dose you missed.

If you use too much SYMTUZA

If you think that you have taken too much SYMTUZA, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using SYMTUZA?

Things you should do

Call your doctor straight away if you:

- **Notice any symptoms of infection.** Tell your doctor immediately if you notice any symptoms of infection. In some patients with advanced HIV infection, signs and symptoms of inflammation from previous infections may occur soon after anti-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.
- **Be sure to keep all your doctor's appointments so your progress can be checked.** Your doctor will want to do some blood, urine and other tests from time to time to check on your progress.

- Be sure to follow up your doctor's instructions about other medicines you should take, and other things you should do.
- If you are undergoing anaesthesia, tell your anaesthetist that you are taking SYMTUZA.

Remind any doctor or pharmacist you visit that you are taking SYMTUZA.

Things you should not do

- Do not stop taking SYMTUZA without talking to your doctor first. HIV therapy may increase your sense of well being. Even when you feel better, do not stop taking SYMTUZA. Talk to your doctor first.

If you have both HIV infection and hepatitis B, it is very important not to stop taking SYMTUZA without talking to your doctor first. You may require blood tests for several months after stopping SYMTUZA treatment. In some patients with advanced liver disease or cirrhosis, stopping SYMTUZA treatment may lead to worsening of hepatitis, which may be life-threatening.
- Avoid doing things that can spread HIV infection since SYMTUZA does not stop you from passing the HIV infection to others:
 - o Do not share needles or other injection equipment.
 - o Do not share personal items that can have blood or body fluids on them, like toothbrushes or razor blades.
 - o Do not have any kind of sex without protection. Always practise safer sex by using a latex or polyurethane condom or other barrier to reduce the chance of passing the infection through semen, vaginal secretions, or blood.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how SYMTUZA affects you.

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

Looking after your medicine

Store below 30°C and in the original package with the dessicant inside the bottle in order to protect the tablets from moisture. Keep the bottle tightly closed. Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

When treating HIV infection, it is not always easy to identify what side effects are caused by SYMTUZA, which are caused by other medicines you are taking, or which are caused by the HIV infection itself.

SYMTUZA 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. See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Infection-related: <ul style="list-style-type: none"> • symptoms of infection such as fever or rashes. Some people with HIV who have had infections in the past may experience a return of symptoms soon after taking anti-HIV medicines. Stomach or gut-related: <ul style="list-style-type: none"> • abdominal pain, diarrhoea • upper abdominal pain that radiates into the back which may be due to inflammation of the pancreas Muscle-related: <ul style="list-style-type: none"> • muscle pain, tenderness or weakness. On rare occasions, these muscle disorders have been serious. Blood-related: <ul style="list-style-type: none"> • increased blood fat levels • raised blood sugar and worsening of diabetes. • SYMTUZA 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. Liver-related: <ul style="list-style-type: none"> • Liver problems that may occasionally be severe have been reported. Signs and symptoms of liver problems 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 	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
<p>sensitivity on your right side below your ribs.</p> <p>Kidney-related:</p> <ul style="list-style-type: none"> new or worsening of kidney problems. <p>Immune-related:</p> <ul style="list-style-type: none"> immune reactivation syndrome. In some patients with advanced HIV infection (AIDS), signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started, including SYMTUZA. <p>Others:</p> <ul style="list-style-type: none"> Fatigue Headache 	
<p>Skin-related:</p> <ul style="list-style-type: none"> Skin rash has been reported in patients receiving SYMTUZA. Although most rashes are mild and disappear after a while when treatment is continued, a rash can occasionally be severe or potentially life-threatening. 	<p>It is important to consult your doctor if you develop a rash. Your doctor will advise you how to deal with your symptoms or whether SYMTUZA must be stopped.</p>

Serious side effects

Serious side effects	What to do
<p>Signs and symptoms of an allergic reaction:</p> <ul style="list-style-type: none"> rash, itching or hives on the skin shortness of breath, wheezing or trouble breathing swelling of the face, lips, tongue or other parts of the body 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What SYMTUZA contains

Active ingredient (main ingredient)	<ul style="list-style-type: none"> darunavir 800 mg (as darunavir ethanolate) cobicistat 150 mg emtricitabine 200 mg tenofovir alafenamide 10 mg (as tenofovir alafenamide fumarate)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> croscarmellose sodium magnesium stearate microcrystalline cellulose silicon dioxide OPADRY II complete film coating system 85F120020 YELLOW (ARTG PI No. 114529)

Do not take this medicine if you are allergic to any of these ingredients.

What SYMTUZA looks like

SYMTUZA 800/150/200/10 film-coated tablet (AUST R 312623): yellow to yellow-brownish capsule-shaped 2.2 x 1.1 cm tablet, debossed with "8121" on one side and "JG" on the opposite side. Each plastic bottle contains 30 tablets. (AUST R 312623).

Who distributes SYMTUZA

Janssen-Cilag Pty Ltd
17 Khartoum Road
Macquarie Park, NSW, 2113
Australia
Telephone: 1800 226 334

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