

# ABACAVEX TABLET/ORAL SOLUTION

(Abacavir Sulfate 300mg USP Tablet, 20mg/ml Oral solution)

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## What Abacavir Sulfate is used for

Abacavir Sulfate is used in antiretroviral combination therapy, for, the treatment of Human Immunodeficiency Virus (HIV) infection in adults and children.

## How Abacavir Sulfate works

The active ingredient Abacavir Sulfate is a potent selective inhibitor of HIV. It works by inhibiting HIV reverse transcriptase enzyme. Reverse transcriptase is an enzyme that HIV needs in order to multiply. Abacavir penetrates the cerebrospinal fluid, and has been shown to reduce HIV-1 RNA levels.

## Before you use Abacavir Sulfate

- When you must not use it

Do not take Abacavir Sulfate if:

- You are allergic or hypersensitive to Abacavir Sulfate or any of the other ingredients of this product.
- You suffer from severe liver impairment

## Pregnancy and lactation

Do not take Abacavir Sulfate if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Abacavir Sulfate if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

## - Before you start to use it

Do not take Abacavir Sulfate if you have:

- Buildup of lactate
- Mitochondrial dysfunction (important part of the cell which fails to produce enough energy for cell or organ function)
- Lipodystrophy (abnormal distribution of fat in the body)
- Pancreatitis (inflammation in the pancreas)
- Liver disease
- Kidney disease
- Hereditary problems of fructose intolerance
- Immune Reactivation Syndrome (some cases of AIDS or immunosuppression, in which the immune system begins to recover, but then responds to a previously acquired opportunistic infection with an inflammatory response that unexpectedly makes the symptoms of infection worse)
- Opportunistic infections (infections that occur more frequently and are more severe in people with weakened immune systems, including people with HIV)
- antiretroviral therapy (medications that treat HIV)
- Autoimmune disorders (Graves disease)
- Osteonecrosis (joint aches and pain, joint stiffness or difficulty in movement.)
- Myocardial infarction

The following hypersensitivity reactions after consuming Abacavir:

- Fever
- Difficulty breathing
- Sore throat
- Cough
- Abnormal chest x-ray findings
- Gastrointestinal symptoms, such as nausea, vomiting, diarrhoea, or abdominal pain, and may lead to misdiagnosis of hypersensitivity

as respiratory disease; pneumonia (infection in one or both lungs), bronchitis (inflammation of the bronchial tubes), pharyngitis (swelling in the back of the throat), or gastroenteritis (stomach flu)

- Lack of energy
- Musculoskeletal symptoms; myalgia (muscle pain), rarely myolysis (destruction of muscle tissue), arthralgia (joint pain)

## - Taking other medicines

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

It is particularly important that you tell your doctor if you are taking or have recently taken:

- Potent enzymatic inducers such as rifampicin (antibiotic), phenobarbital and phenytoin (both drug controls seizures)

## How to use Abacavir Sulfate

- How much to use

Adults and adolescents weighing at least 30kg:

The recommended dose of abacavir sulfate tablets/ oral solution is 600 mg (30ml) daily.

- This may be administered as either 300 mg (one tablet) (15ml) twice daily or 600 mg (two tablets) (30ml) once daily.
- Patients changing to the once daily regimen should take 300 mg (15ml) twice a day and switch to 600 mg (30ml) once a day the following morning.
- Where an evening once daily regimen is preferred, 300 mg (15ml) of abacavir sulfate tablets/ oral solution should be taken on the first morning only, followed by 600 mg (30ml) in the evening.
- When changing back to a twice daily regimen, patients should complete the day's treatment and start 300 mg (15ml) twice a day the following morning.

Children

The dose will be adjusted by doctor according to the weight of the children.

Kidney impairment:

No dosage adjustment of abacavir sulfate tablets/ oral solution is necessary in patients with renal impairment. However, abacavir sulfate tablets should be avoided in individuals with end-stage renal disease.

Liver impairment:

In individuals with mild and moderate hepatic impairment close monitoring is required, and if feasible, monitoring of abacavir plasma levels is recommended. Abacavir is contraindicated in patients with severe hepatic impairment.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Abacavir Sulfate for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

**While you are using it**

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Abacavir Sulfate Tablet.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Abacavir Sulfate to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

**Side effects**

Like all medicines, Abacavir Sulfate can cause side effects, although not everybody gets them.

Tell your doctor or pharmacist immediately if you experience any of the following side effects after taking this medicine as the symptoms can be severe.

- Rash
- Stomach and Intestine  
Nausea, vomiting, diarrhoea, abdominal pain, mouth ulceration
- Respiratory tract  
Difficulty breathing, cough, sore throat, adult respiratory distress

syndrome (fluid fills up the air sacs in the lungs), respiratory failure (inability to breathe)

- Miscellaneous  
Fever, tiredness, uneasiness, fluid retention, enlargement of the lymph nodes in response to regional infection or inflammation, low blood pressure, inflammation of the conjunctiva, severe allergic reaction.
- Neurological/Psychiatry  
Headache, pricking, burning, tingling or numbing sensation
- Blood  
Loss of white blood cells called lymphocytes
- Liver/pancreas  
Elevated liver function tests, hepatitis (viral infection), liver failure
- Musculoskeletal  
Muscle pain, destruction of muscle tissue, joint pain, elevated creatine phosphokinase (enzyme that is found in your heart, brain and skeletal muscles)
- Kidney failure/impairment
- General disorders (fever, lethargy, fatigue)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.moh.gov.my](http://npra.moh.gov.my) (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

**Storage and Disposal of Abacavir Sulfate Tablet**

- Storage

Keep out of the reach and sight of children.

Store in a dry place and below 30°C and protect from light.

- Disposal

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

**Product Description**

- What it looks like

Abacavir Sufate USP Tablets 300mg:

Yellow coloured, biconvex, capsule shaped coated tablets, debossed with 'D' and '88' on either side of the scoreline on one side and plain with a score line on other side.

Abacavir Sulfate 20mg/ml Oral Solution:

Clear to opalescent yellowish, strawberry-banana flavoured liquid.

- Ingredients

- Active ingredient(s)  
Abacavir Sulfate

- Inactive ingredients

Abacavir Sufate USP Tablets 300mg:

Magnesium Stearate, Sodium Starch Glycolate, Microcrystalline Cellulose, Colloidal Silicon Dioxide, Opadry Yellow and Purified Water.

Abacavir Sulfate 20mg/ml Oral Solution:

Saccharin Sodium, Propyl Paraben, Methyl Paraben, Sodium citrate, dehydrate, Noncrystallizing Sorbitol solution, citric acid anhydrous, propylene glycol, Banana Flavour, Strawberry Flavour and Purified Water.

- MAL number(s):

**Abacavir Sufate USP Tablets 300mg:**

MAL10100007AZ

**Abacavir Sulfate 20mg/ml Oral Solution:**

MAL09122043AZ

**Manufacturer**

Aurobindo Pharma Limited  
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Bachupally, Bachupally Mandal,  
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**Product Registration Holder**

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24/04/2020

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