

GRATEZIANO 400 MG FILM COATED TABLET

Sofosbuvir (400 mg)

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What GRATEZIANO is used for

GRATEZIANO is used in combination with other medicine for treatment of hepatitis C virus infection in adults.

How GRATEZIANO works

GRATEZIANO contains sofosbuvir, a medicine that treat hepatitis C virus infection. It works by lowering the amount of hepatitis C virus in the body and removing the virus from the blood over a period of time.

GRATEZIANO is commonly taken with either ribavirin or peginterferon alfa and ribavirin.

Before you use GRATEZIANO

- When you must not use it

If allergic (hypersensitive) to the sofosbuvir or to any of the other ingredients of GRATEZIANO.

If you are taking any of the following medicines:

- Rifampin (antibiotic used to treat bacterial infection including tuberculosis)
- St. John's wort (Hypericum perforatum – herbal medicine used to treat depression)
- Carbamazepine, phenobarbital and phenytoin (medicine used to treat epilepsy and prevent seizures)

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

- Before you start to use it

Discuss with your doctor or pharmacist if:

- You are taking amiodarone (medicine used to treat and prevent irregular heartbeats).
- You have a current or previous hepatitis B infection.
- You have liver problem.
- You have diabetes.

Pregnancy and lactation

Do not take GRATEZIANO with ribavirin if you are pregnant, trying to get pregnant or think you may be pregnant. Ribavirin may cause damage to unborn baby. Extreme caution must be taken to avoid pregnancy while taking this combination.

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

Driving and use machines

When taking GRATEZIANO together with other medicines for the treatment of hepatitis C infection, patients have reported tiredness, dizziness, blurred vision and reduced attention. If you have any of these side effects, do not drive or use any tools or machines.

- Taking other medicines

Tell your doctor if you are taking any other medicines as below:

- Antiarrhythmics (medicine that relieves or prevents irregular heart rhythms) - Amiodarone
- Anticonvulsants (medicine that used to control seizures) – carbamazepine, phenytoin, phenobarbital, oxcarbazepine
- Medicine used to thin the blood – warfarin and other similar medicines called vitamin K antagonists
- Medicine to treat people with narcolepsy (condition characterized by an extreme tendency to fall asleep – modafinil)
- Antimycobacterials (medicine used to treat bacteria infection i.e. Mycobacteria) – rifabutin, rifapentine

How to use GRATEZIANO

- How much to use

The recommended dose is one tablet once a day with food.

Swallow the tablet whole. Do not chew or crushed the tablet as it has a very bitter taste.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking GRATEZIANO for as long as your doctor or pharmacist recommends.

- If you forget to use it

It is important not to miss a dose of this medicine.

If you do miss a dose:

- and you notice within 18 hours of the time you usually take GRATEZIANO, you must take the tablet as soon as possible. Then take the next dose at your usual time.
- and you notice 18 hours or more after the time you usually take GRATEZIANO, wait and take the next dose at your usual time. Do not take a double dose (two doses close together).

- If you use too much (overdose)

If overdosage occurs, patient must be monitored for evidence of toxicity. Treatment consists of general supportive measures including monitoring vital signs as well as the observation of the clinical status of the patient.

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 GRATEZIANO.

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 GRATEZIANO to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

You should not breastfeed during treatment with GRATEZIANO. It is not known whether GRATEZIANO are present in human breast milk.

Side effects

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

Tell your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

When you take GRATEZIANO in combination with amiodarone (medicine used for heart problem), you may get one or more of the side effects below:

- slow or irregular heartbeat or heart rhythm problems.
- Shortness of breath or worsening of any shortness of breath you already have.

When you take GRATEZIANO with ribavirin or both peginterferon alfa and ribavirin, you may get one or more of the side effects below:

Very common side effects

- fever, chills, flu-like symptoms
- nausea, diarrhoea, vomiting
- headache
- insomnia (sleeping trouble)
- joint pain and muscle pain
- feeling tired and irritable
- rash, itchy skin
- changes in liver (as shown by increased amounts of substance called bilirubin in the blood)
- cough, shortness of breath
- dizziness
- lack of appetite

- anaemia (low red blood cell count)
- neutropenia (low white blood cell count)
- low blood platelet count

Common side effects

- chest pain, feeling weak
- back pain, muscle spasms
- dry skin, hair loss or thinning of hair
- stomach discomfort, constipation, dry mouth, indigestion, acid reflux
- shortness of breath during exercise
- blurred vision
- migraine, memory loss, disturbance in attention
- feeling depressed, anxious and agitated
- weight loss
- nasopharyngitis (getting a cold)

Other side effects that may be seen during the treatment with sofosbuvir:

The frequency is not known

- wide spread severe rash with peeling skin which may be accompanied by fever, flu like symptoms, blisters in the mouth, eyes, and/or genitals (Stevens-Johnson syndrome)

If any of the side effects gets serious, please tell your doctor or pharmacist.

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.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of GRATEZIANO

- Storage

Keep medicine out of reach of children.

Store at room temperature not exceeding 30°C, in a dry place.

Dispense only in original container.

Do not use if seal over bottle opening is broken or missing.

- 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

GRATEZIANO tablets are pale yellow to yellow oblong biconvex film-coated tablet.

- Ingredients

- Active ingredient(s)
Sofosbuvir 400 mg

- Inactive ingredients

Mannitol, Microcrystalline cellulose, Croscarmellose sodium, Colloidal silicon dioxide, Magnesium stearate, Opadry 85F92259 (Polyvinyl alcohol, Iron oxide yellow, Talc, Macrogol (Polyethylene glycol), Titanium dioxide).

- MAL number:

MALXXXXXXXXXAZ

Manufacturer

European Egyptian Pharmaceutical Industries

Amriya, Alexandria-Cairo Desert Road, P.O Box 111 El Mansheya, Alexandria, Egypt

Product Registration Holder

Pharmaniaga Logistics Sdn. Bhd.
No 7 Lorong Keluli 1B, Kawasan Perindustrian Bukit Raja Selatan, Seksyen 7, 40 000 Shah Alam, Selangor

Date of Revision

10/06/2020

Serial Number

NPRA (R2) 20/044