

JUBITEL (Telmisartan Tablets 40mg & 80mg)

Telmisartan (40mg & 80mg)

What is in this leaflet

1. What JUBITEL is used for
2. How JUBITEL works
3. Before you use JUBITEL
4. How to use JUBITEL
5. While you are using it
6. Side effects
7. Storage and Disposal of JUBITEL
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What is JUBITEL used for

JUBITEL is used to treat high blood pressure. It is also used to reduce your risk of cardiovascular events such as a heart attack, stroke or death from cardiovascular causes in patients 55 years or older at high risk of developing major cardiovascular events who are unable to take a group of medicines called ACE inhibitors.

JUBITEL can be used in addition to other needed treatment such as for blood pressure, anti-blood clotting or cholesterol lowering therapy.

How JUBITEL works

JUBITEL works by blocking a receptor called angiotensin II receptor. Angiotensin II is a substance produced in your body which causes your blood vessels to narrow, thus increasing your blood pressure. Telmisartan blocks the effect of angiotensin II so that the blood vessels relax, and your blood pressure is lowered.

Before you use JUBITEL

-When you must not use it

Do not use JUBITEL if you are allergic to Telmisartan or any other ingredients in this medication.

If you are more than 3 months pregnant. It is best to avoid this medication in early pregnancy.

If you have severe liver problems such as cholestasis or biliary obstruction (problems with drainage of the bile from the liver and gall bladder) or any other severe liver disease.

If you are diabetic or have renal (kidney) disease and are on a high blood pressure medication called Aliskiren.

If you are breastfeeding.

-Before you start to use it

Please tell your doctor if you are suffering or have ever suffered from any of the following conditions or illnesses:

- Kidney disease or kidney transplant
- Renal artery stenosis (narrowing of the blood vessels to one or both kidneys)
- Liver disease
- Heart troubles
- Raised aldosterone levels (water and salt retention in the body along with imbalance of various blood minerals)
- Low blood pressure (hypotension), likely to occur if you are dehydrated or have salt deficiency due to diuretic therapy ('water tablets'), low salt diet, diarrhoea or vomiting
- Elevated potassium levels in your blood
- Diabetes

Tell your doctor if you are or might become pregnant. This medication can cause harm to your baby if used after 3 months of pregnancy.

Tell your doctor if you are planned to undergo surgery or anaesthesia.

The use of JUBITEL in children and adolescents up to the age of 18 years is not recommended.

As with all other angiotensin antagonists, JUBITEL may be less effective in lowering the blood pressure in black patients.

-Taking other medications

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines including those you buy without a prescription, from the supermarket or health food stores. Your doctor may need to change the dose of these other medicines or take other precautions. This applies especially to the medicines listed below:

- Lithium containing medicines to treat some types of depression
- Medicines that may increase blood potassium levels such as salt substitutes containing potassium, potassium-sparing diuretics (certain 'water tablets'), ACE inhibitors, angiotensin II receptor antagonists, NSAIDs (non-steroidal anti-inflammatory drugs e.g. aspirin or ibuprofen), heparin, immunosuppressives (e.g. cyclosporin or tacrolimus) and the antibiotic trimethoprim
- Diuretics ('water tablets'), especially if taken in high doses together with JUBITEL, may lead to excessive loss of body water and low blood pressure (hypotension)

As with other blood pressure lowering medicines, the effect of JUBITEL may be reduced when you take NSAIDs or corticosteroids. JUBITEL may increase the blood pressure lowering effect of other medicines used to treat high blood pressure.

How to use JUBITEL

-How much to use

Always take JUBITEL exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

The usual dose of JUBITEL is one tablet a day at the same time each day. You can take it with or without

JUBITEL (Telmisartan Tablets 40mg & 80mg)

Telmisartan (40mg & 80mg)

food, swallowed whole with some water. It is important that you take this medication everyday as your doctor recommends.

For treatment of high blood pressure, the usual starting dose is one 40mg tablet daily. However, your doctor may recommend a higher dose of 80mg. Alternatively, JUBITEL may be used in combination with diuretics ('water tablets') such as hydrochlorothiazide which has been shown to have an additive blood pressure lowering effect with Telmisartan.

For reduction of cardiovascular events, the usual dose of JUBITEL is one 80mg tablet daily. At the beginning of the preventive therapy with JUBITEL, blood pressure should be frequently monitored.

If your liver is not working properly, the usual dose should not exceed 40mg once daily.

-When to use it

Use it as your doctor recommends. Do not stop taking this medication without consulting your doctor first.

-How long to use it

Use it for as long as your doctor recommends. Do not stop taking this medication without consulting your doctor first.

-If you forget to use it

If you forget to take it, take it as soon as you remember. If it is time for your next dose, skip the forgotten dose and take your next dose as usual. Do not double the dose to make up the forgotten dose.

-If you use too much (overdose)

If you accidentally take too many tablets, contact your doctor, pharmacist or your nearest hospital emergency department immediately.

While you are using it

-Things you must do

Take JUBITEL according to your doctor's instructions. Tell your

doctor or pharmacist if any side effect become serious, or if you notice any side effects not listed in this leaflet.

-Things you must not do

Do not stop taking JUBITEL unless advised by your doctor

-Things to be careful of

Pregnancy and breastfeeding: Tell your doctor if you are pregnant or plan to start a family. JUBITEL is not recommended to be taken while pregnant, especially after the third month onwards. Your doctor will advise you to take another medication to control your blood pressure. JUBITEL is not recommended for breast-feeding mothers. Your doctor will choose an alternative medication for you to take.

Driving and using machines: JUBITEL may or may not cause drowsiness. If you feel drowsy after taking this medication, stop driving or operating machinery.

Side effects

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

Some side effects reported while on Telmisartan are as follows:

- Upper respiratory tract infection including pharyngitis and sinusitis, urinary tract infections
- Anxiety, depression, insomnia, drowsiness
- Hypoglycaemia (low blood sugar levels) in diabetic patients
- Slow or fast heartbeat, low blood pressure, fainting, dizziness
- Abdominal pain, diarrhoea, vomiting, cough
- Itchy skin, rashes
- Chest pain or flu-like illness
- Anaemia
- Allergic reaction
- Increased blood potassium levels

- Visual disturbances
- Liver disorders
- Increase in blood creatinine (a waste product)

You may refer the full side effects list in the package insert of this product.

If you notice any other unusual side effects while taking JUBITEL, please inform your doctor or pharmacist.

You may report any side effects or adverse drug reaction directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835549, or visiting the website npra.moh.gov.my (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI))

Storage and Disposal of JUBITEL

-Storage

Store below 30°C. Keep out of reach of children.

-Disposal

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

Product Description

-What it looks like

JUBITEL (Telmisartan Tablets 40mg): White to off-white, capsule shaped tablets debossed with 'H' on one side and plain on the other side.

JUBITEL (Telmisartan Tablets 80mg): White to off-white, capsule shaped tablets debossed with 'D' on one side and plain on the other side.

JUBITEL (Telmisartan Tablets 40mg & 80mg)

Telmisartan (40mg & 80mg)

-Ingredients

- Active ingredient(s)

Telmisartan

- Inactive ingredient(s)

Meglumine, sodium
hydroxide, povidone,
purified water, mannitol,
magnesium stearate

-MAL number

MALXXXXXXXXXAZ

Manufacturer

Jubilant Generics Limited
Village Sikandarpur Bhainswal,
Roorkee-Dehradun Highway,
Bhagwanpur, Roorkee Distt.
Haridwar, Uttarakhand 247661 India

Product Registration Holder

Healol Pharmaceuticals Sdn. Bhd
74-3, Jalan Wangsa Delima 6,
KLSC Wangsa Maju,
53300 Kuala Lumpur, Malaysia

Date of revision

-01/11/2018

Serial Number

NPRA(R2)19/62