

OPSYNVI®

Macitentan and Tadalafil (10mg/20mg; 10mg/40mg)

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What OPSYNVI® is used for

OPSYNVI® is a prescription medicine that contains 2 medicines called macitentan and tadalafil.

OPSYNVI® is used for long-term treatment of adults with pulmonary arterial hypertension (PAH), which is high blood pressure in the arteries of your lungs.

How OPSYNVI® works

OPSYNVI® widens the pulmonary arteries, making it easier for the heart to pump blood through them. This lowers the blood pressure in the blood vessels that carry blood from the heart to the lungs (pulmonary arteries) and may improve some of your symptoms.

Before you use OPSYNVI®

- When you must not use it

Do not take OPSYNVI® if you

- are pregnant, plan to become pregnant, or become pregnant during treatment with OPSYNVI®. OPSYNVI® can cause serious birth defects
- are allergic to macitentan, tadalafil, or any of the other ingredients in OPSYNVI®.
- take any medicines called nitrates.
take any medicines called guanylate cyclase (GC) stimulators.

If any of these apply to you, please tell your doctor.

- Before you start to use it

Before taking OPSYNVI®, tell your doctor about all of your medical conditions, including if you:

- have liver problems
- have low blood pressure
- have anemia
- have heart problems including heart attack or heart failure
- have pulmonary veno-occlusive disease (PVOD)
- have any eye problems, including NAION or an inherited eye disorder called retinitis pigmentosa
- have hearing problems such as ringing in the ears, dizziness, or loss of hearing
- have a deformed penis shape or Peyronie's disease or have blood cell problems such as sickle cell anemia, multiple myeloma, or leukemia. These conditions increase your risk of getting a prolonged erection.
- have kidney problems or get dialysis
- are pregnant or plan to become pregnant during OPSYNVI® treatment.
- are breastfeeding or plan to breast feed.

Talk to your doctor or pharmacist before using OPSYNVI®.

Your doctor will take blood before you start treatment with OPSYNVI® and during treatment to test:

- whether you have anemia (a reduced number of red blood cells)
- whether your liver is working properly

Pregnancy and lactation

Do not take OPSYNVI® if you are pregnant or breastfeeding. If you are planning to have a baby, ask your doctor for advice before taking this medicine.

OPSYNVI® can cause serious birth defects if taken during pregnancy.

- Females should not be pregnant when they start taking OPSYNVI® or become pregnant

during treatment with OPSYNVI®.

- Females who are able to get pregnant should have a negative pregnancy test before beginning treatment with OPSYNVI®. Talk to your doctor about your menstrual cycle. Your doctor will decide when to do the pregnancy test and will order a pregnancy test for you depending on your menstrual cycle.
- Females who are able to get pregnant should use effective birth control before starting treatment with OPSYNVI®, during treatment, and for 1 month after stopping OPSYNVI® because the medicine may still be in the body.
- Talk with your doctor or gynecologist (a doctor who specializes in female reproduction) to find out about options for acceptable birth control that you may use to prevent pregnancy during treatment with OPSYNVI®.
- If you decide that you want to change the form of birth control that you use, talk with your doctor or gynecologist to be sure that you choose another acceptable form of birth control.
- Do not have unprotected sex. Talk to your doctor or pharmacist right away if you have unprotected sex or if you think your birth control has failed. Your doctor may talk with you about using emergency birth control.
- Tell your doctor right away if you miss a menstrual period or think you may be pregnant.

If you are a female who can get pregnant, you should talk to your doctor to understand the benefits and risks of OPSYNVI®.

Children and adolescents

Do not give OPSYNVI® to children or young people below 18 years of age because it has not been tested in children.

- Taking other medicines

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Tell your doctor or pharmacist about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking OPSYNVI® with other medicines may affect the way OPSYNVI® and the other medicines work, and may increase your risk of side effects. Do not start any new medicine until you check with your doctor or pharmacist.

Please talk to your doctor or pharmacist if you are taking any of the following medicines:

- nitrate medicines
- HIV medicines
- antifungal medicines
- antiseizure medicines
- medicines used to treat infection
- erectile dysfunction medicines
- blood pressure medicines
- medicines used to treat PAH or heart problems

Do not have more than 4 alcohol-containing drinks in a short period of time during treatment with OPSYNVI. Drinking too much alcohol can increase your chances of getting low blood pressure, increased heart rate, dizziness, and headache.

How to use OPSYNVI®

OPSYNVI® should only be prescribed by a doctor experienced in the treatment of pulmonary arterial hypertension.

- How much to use

The recommended maintenance dose of OPSYNVI® is one 10 mg/ 40 mg tablet, once a day. In some situations your doctor may start you on a 10 mg/ 20 mg dose, taken daily for one week. If tolerated, your doctor will increase your dose to the recommended maintenance dose of one 10 mg/ 40 mg tablet, once a day. This is called titration. It lets your body adjust to the new medicine. Your maintenance dose is the dose you should continue to take on a regular basis.

- When to use it

Swallow the whole tablet, with a glass of water. Do not chew or break the tablet. You can take OPSYNVI® with or without food. It is best to take the tablet at the same time each day.

- How long to use it

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

- If you forget to use it

If you forget to take OPSYNVI®, take a dose as soon as you remember, then continue to take your tablets at the usual times. Do not take a double dose to make up for a forgotten tablet.

- If you use too much (overdose)

Contact your doctor or pharmacist immediately. You may experience any of the side effects described in “Side effects” section.

While you are using OPSYNVI®

- Things you must do

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using OPSYNVI®.

Tell your doctor immediately if you become pregnant while using this medication

- Things you must not do

OPSYNVI® is a treatment that you will need to keep on taking to control your PAH. Do not stop taking OPSYNVI® unless you have agreed this with your doctor.

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

- Things to be careful of

Driving and using machines

No studies on the effect of OPSYNVI® on the ability to drive and use machines have been performed. OPSYNVI® can cause side effects such as headaches and dizziness. Check carefully how you react to the

medicines before driving or using any machinery.

Side Effects

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

OPSYNVI® can cause serious side effects, including:

- Serious birth defects. See “Pregnancy and lactation”
- Liver problems. Tell your doctor if you have any of the following symptoms of liver problems during treatment with OPSYNVI®.
 - nausea or vomiting
 - yellowing of your skin or whites of your eyes
 - pain in the upper right stomach
 - tiredness
 - loss of appetite
 - dark urine
 - fever
 - itching
- Decreased blood pressure (hypotension)
- Low red blood cell levels (anemia), usually during the first weeks after starting therapy.
- Vision loss.
- Hearing problems. Sudden decrease or loss of hearing, ringing in the ears and dizziness,
- Fluid retention, unusual weight gain, trouble breathing, or swelling of your ankles or legs
- Decreased sperm count
- Prolonged erection, painful erections (priapism)

The most common side effects of OPSYNVI® include:

- too much fluid in your body (fluid retention) and swelling caused by too much fluid (edema)
- anemia
- headache, including migraine headache

These are not all the possible side effects of OPSYNVI®. Call your doctor for medical advice about side effects.

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

Storage and Disposal of OPSYNVI®

- Storage

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

Do not use OPSYNVI after the expiry date which is stated on the carton bottle or blister after “EXP”. The expiry date refers to the last day of that month.

Store below 30 °C in original package.

- 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

OPSYNVI® 10 mg macitentan/20 mg tadalafil tablets

Pink, oblong-shaped, film-coated tablets with “1020” on one side and “MT” on the other side.

OPSYNVI® 10 mg macitentan/40 mg tadalafil tablets

White to almost-white, oblong-shaped, film-coated tablets with “1040” on one side and “MT” on the other side.

OPSYNVI® 10 mg macitentan/20 mg tadalafil tablets are supplied in blister containing 7 tablets.

OPSYNVI® 10 mg macitentan/40 mg tadalafil tablets are supplied in blisters containing 30 tablets.

- Ingredients

- Active ingredients

OPSYNVI® 10 mg macitentan/20 mg tadalafil tablets

Each film coated tablets contain 10 mg of macitentan and 20 mg of tadalafil

OPSYNVI® 10 mg macitentan/40 mg tadalafil tablets

Each film coated tablets contain 10 mg of macitentan and 40 mg of tadalafil

- Inactive ingredients

OPSYNVI® 10 mg macitentan/20 mg tadalafil tablets

Tablet core: hydroxypropylcellulose, lactose monohydrate, low-substituted hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, polysorbate 80, povidone, sodium starch glycolate, and sodium lauryl sulfate

Film coating: hydroxypropyl methylcellulose, lactose monohydrate, titanium dioxide, triacetin and talc. The 10 mg/20 mg also contains iron oxide yellow and iron oxide red.

OPSYNVI® 10 mg macitentan/40 mg tadalafil tablets

Tablet core: hydroxypropylcellulose, lactose monohydrate, low-substituted hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, polysorbate 80, povidone, sodium starch glycolate, and sodium lauryl sulfate

Film coating: hydroxypropyl methylcellulose, lactose monohydrate, titanium dioxide, triacetin and talc. The 10 mg/20 mg also contains iron oxide yellow and iron oxide red.

- MAL number(s):

10 mg/20 mg: MAL XXXXXXXXXXXX
10 mg/40 mg: MAL XXXXXXXXXXXX

Manufacturer

Penn Pharmaceutical Services Limited
Units 23-24, Tafarnaubach Industrial Estate Tafarnaubach, Tredegar, Gwent NP22 3AA United Kingdom.

Product Registration Holder

Johnson & Johnson Sdn Bhd (3718-D)
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Date of Revision

1/7/2026 (MY PI based on USPI v2Apr2025)

Serial Number

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