

Approved Patient Information Leaflet for OMNOPON 20 FRESENIUS

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S6

OMNOPON 20 FRESENIUS solution for injection
Morphine hydrochloride, papaverine hydrochloride,
codeine hydrochloride
Sugar free

Read all of this leaflet carefully before you receive OMNOPON 20 FRESENIUS:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet:

1. What OMNOPON 20 FRESENIUS is and what it is used for
2. What you need to know before you receive OMNOPON 20 FRESENIUS
3. How to receive OMNOPON 20 FRESENIUS
4. Possible side effects
5. How to store OMNOPON 20 FRESENIUS
6. Contents of the pack and other information

1. What OMNOPON 20 FRESENIUS is and what it is used for

OMNOPON 20 FRESENIUS contains 3 opioid types of medicines namely morphine, papaverine and codeine. Morphine and codeine are two powerful medicines with pain relieving properties. Papaverine is a smooth muscle relaxant.

OMNOPON 20 FRESENIUS is used:

- For the relief of severe or very severe pain, before and just after an operation.
- To treat coughing or wheezing that occurs with heart failure (when your heart muscle doesn't pump blood as well as it should).
- To treat pulmonary oedema (a condition caused by excess fluid in the lungs, making it difficult to breathe).
- To treat coronary occlusion (a condition where there is a partial or complete obstruction of blood flow in a coronary artery).
- To treat pulmonary embolism (a blood clot that occurs in the lung).

2. What you need to know before you receive OMNOPON 20 FRESENIUS

OMNOPON 20 FRESENIUS should not be given to you if you:

- Are hypersensitive (allergic) to morphine, papaverine, codeine or any of the other ingredients of OMNOPON 20 FRESENIUS (listed in section 6 of this leaflet).
- Are suffering from breathing difficulties such as asthma or if you are having an asthma attack.
- Are in a coma.
- Suffer from alcoholism.
- Suffer from fits or seizures.
- Have suffered a head injury or are experiencing severe and undiagnosed headaches.
- Have stomach pains.
- Suffer from heart failure (when your heart muscle doesn't pump blood as well as it should) that resulted from lung disease.
- Suffer from a tumour of the adrenal gland (phaeochromocytoma).
- Suffer from obstruction of the intestine due to paralysis of the intestinal muscles (paralytic ileus).
- Are currently taking medicines known as monoamine oxidase inhibitors (see section "Other medicines and OMNOPON 20 FRESENIUS").
- Suffer from atrioventricular block (a condition where the electrical signal that controls the heartbeat is partially or completely blocked).

Warnings and precautions:

Talk to your doctor before receiving OMNOPON 20 FRESENIUS if you:

- Suffer from opioid addiction.
- Suffer from thyroid problems.
- Suffer from problems with your adrenal glands.
- Have liver or kidney problems.
- Are a male patient having problems with your prostate.
- Suffer from low blood pressure.
- Are in shock (with symptoms such as sweating, a fast pulse and cold, clammy skin).
- Suffer from bowel problems.
- Suffer from myasthenia gravis (a disease that leads to muscle weakness and rapid fatigue of muscles under voluntary control).
- Have an unusually fast heartbeat.
- Suffer from any heart disorders.
- Are in labour.

Take special care with OMNOPON 20 FRESENIUS if you:

- Are elderly or very ill.
- Experience any shortness of breath.

Taking opioids or receiving opioids (as contained in OMNOPON 20 FRESENIUS) over a long period of time produces:

- Tolerance (where you develop a requirement for increased doses of OMNOPON 20 FRESENIUS to achieve the same pain-relieving effects).
- Dependence, such that when people stop taking/receiving opioids, they have physical and psychological symptoms of withdrawal (such as muscle cramping, diarrhoea, and anxiety).

Opioid addiction can cause life-threatening health problems, including the risk of overdose. Speak to your doctor if you experience any of these effects or if you are concerned.

Children and adolescents:

Great care should be taken if OMNOPON 20 FRESENIUS is given to newborns or babies, as they may be more sensitive to breathing difficulties associated with OMNOPON 20 FRESENIUS use.

Other medicines and OMNOPON 20 FRESENIUS:

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

OMNOPON 20 FRESENIUS should not be used together with medicines known as monoamine oxidase inhibitors (MAOIs), or if you are within 2 weeks of discontinuing them. MAOIs are medicines, such as moclobemide, phenelzine and selegiline, that are used to treat severe depression.

Concomitant use of OMNOPON 20 FRESENIUS and sedative medicines such as benzodiazepines or related medicines increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However, if your doctor does prescribe OMNOPON 20 FRESENIUS together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Tell your doctor if you are taking any of the following medicines:

- Medicines used to reduce anxiety (anxiolytics).
- Medicines used to help you to sleep (hypnotics).
- CNS depressants (medicines that act on the brain and make you feel drowsy or faint). These include sleeping pills, antihistamines (medicines used to treat allergies) that make you drowsy, medicines used to treat certain mental disorders (such as tricyclic antidepressants), other painkillers or general anaesthetics.

- Medicines used to treat mental disorders (antipsychotics).
- Metoclopramide, a medicine used to treat nausea and vomiting.
- Ciprofloxacin, a medicine used to treat bacterial infections.

OMNOPON 20 FRESENIUS with food and drink:

OMNOPON 20 FRESENIUS should not be used together with alcohol containing drinks (also see “OMNOPON 20 FRESENIUS should not be given to you if you”).

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving OMNOPON 20 FRESENIUS.

Driving and using machines:

OMNOPON 20 FRESENIUS may cause drowsiness and impair your reaction and reflexes. If you are affected do not drive or use machines.

OMNOPON 20 FRESENIUS contains ethyl alcohol (ethanol):

OMNOPON 20 FRESENIUS contains 50,88 mg ethyl alcohol per dosage unit. The small amount of alcohol in OMNOPON 20 FRESENIUS will not have any noticeable effects.

3. How to receive OMNOPON 20 FRESENIUS

Do not share any medicines prescribed for you with any other person.

You will not be expected to give yourself OMNOPON 20 FRESENIUS. It will be given to you by a doctor or a person who is qualified to do so.

OMNOPON 20 FRESENIUS will be given to you as an injection into a vein (intravenously), under the skin (subcutaneously) or into a muscle (intramuscularly).

Your doctor will tell you how long your treatment with OMNOPON 20 FRESENIUS will last. If you have the impression that the effect of OMNOPON 20 FRESENIUS is too strong or too weak, tell your doctor or pharmacist.

If you receive more OMNOPON 20 FRESENIUS than you should:

Since a health care provider will administer OMNOPON 20 FRESENIUS he/she will control the dosage. However, in the event of overdosage, your doctor will manage the overdose.

If a dose of OMNOPON 20 FRESENIUS is missed:

Since a health care provider will administer OMNOPON 20 FRESENIUS, it is unlikely that the dose will be missed.

4. Possible side effects

OMNOPON 20 FRESENIUS can have side effects.

Not all side effects reported for OMNOPON 20 FRESENIUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using OMNOPON 20 FRESENIUS, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop receiving OMNOPON 20 FRESENIUS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to OMNOPON 20 FRESENIUS. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Tolerance or dependence to OMNOPON 20 FRESENIUS (see section “Warnings and precautions”).
- Mood changes, confusion, hallucinations (seeing or hearing things that are not real).
- Seizures (fits).
- Faster or slower heartbeat than usual.
- Slowed breathing or difficulty breathing.
- Yellowing of skin or whites of the eyes (jaundice).
- Difficulty passing urine.
- Hypothermia (a dangerous drop in body temperature, with symptoms such as shivering, drowsiness and feeling weak).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Nausea, vomiting, loss of appetite.
- Dry mouth, headache, drowsiness.
- A feeling of spinning (vertigo).
- Pinpoint pupils.
- Facial flushing.
- Feeling faint on standing up from a seated position.
- Low blood pressure.
- Reduced sex drive.
- Skin itching or rash, pain or irritation at the injection site.

Frequency not known:

- Dizziness, restlessness.
- Muscle tension, stiffness or muscle pain.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of OMNOPON 20 FRESENIUS.

Health care providers are asked to report any suspected adverse drug reactions to the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine’s regulatory authority in the country where the product is marketed.

5. How to store OMNOPON 20 FRESENIUS

- Protect from light and store at or below 25 °C.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What OMNOPON 20 FRESENIUS contains:

The active ingredients are morphine hydrochloride, papaverine hydrochloride and codeine hydrochloride.

Each 1 ml solution of OMNOPON 20 FRESENIUS per ampoule contains: 13,44 mg morphine hydrochloride; 1,20 mg papaverine hydrochloride and 1,04 mg codeine hydrochloride.

The other ingredients are glacial acetic acid (for pH-adjustment), water for injection and sodium hydroxide (for pH-adjustment).

OMNOPON 20 FRESENIUS also contains 6,44 % v/v ethyl alcohol, which is equivalent to 50,88 mg ethyl alcohol per dosage unit.

What OMNOPON 20 FRESENIUS looks like and contents of the pack:

A clear, colourless to yellowish-brown solution in colourless ampoules.

1 ml clear glass OPC ampoule, with a blue ring above the neck, containing 1 ml of solution, packed into a blister tray and outer carton.

Pack size: 10 ampoules per outer carton.

Holder of certificate of registration and manufacturer:

Fresenius Kabi Manufacturing SA (Pty) Ltd

6 Gibaud Road

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This leaflet was last revised:

24 May 2022

Registration number:

B1006 (Act 101/1965)