Ondansetron-Claris

Ondansetron hydrochloride dihydrate equivalent to Ondansetron 2 mg/mL, Solution for Injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common queries about Ondansetron-Claris solution for injection. It does not contain all the available information. If you have any further queries or concerns about this medicine, talk to you doctor or pharmacist.

Keep this leaflet. You may need to refer to it again.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Ondansetron-Claris against the benefits it is expected to have for you.

What Ondansetron-Claris is used for

Ondansetron is used to help stop the nausea and vomiting which can occur after medical treatments and operations.

It belongs to a group of medicines known as serotonin receptor-3 antagonists. It should only be used to treat the nausea and vomiting for which it has been prescribed.

Your doctor may have prescribed

Ondansetron-Claris for you for another reason.

Ask you doctor if you have any queries about why Ondansetron-Claris was prescribed for you.

Before you take Ondansetron-Claris

When you must not take it

- If you have ever had an allergic reaction to ondansetron or any of the other ingredients used in this medicine (listed under the heading Other Ingredients)
- If you are pregnant, trying to become pregnant or are breast feeding, unless your doctor has advised it is safe to do so.
- the expiry date (EXP) printed on the pack has passed.
- the solution is coloured, cloudy or lumpy
- if the packaging is damaged or shows of tampering

Before you start to take the medicine

Tell vour doctor if:

- you have any allergies to other
- medicines, foods, preservatives or dyes.you have had to stop taking another
- medicine for nausea or vomiting.
 you are pregnant, planning to become pregnant or are breastfeeding. You and your doctor can then discuss the
- potential risks and benefits involved.
 you have or used to have liver problems
 Tell you doctor or pharmacist if you are taking any other medicines including any you can obtain without a prescription from a pharmacy, supermarket or health

shop. Some medicines and Ondansetron Hydrochloride affect how each other works when taken at the same time. The amount you take may need to be changed.

How to use the Medicine

Ondansetron-Claris Solution for Injection can only be given by a doctor or nurse. Do

NOT use Ondansetron-Claris Solution for Injection on your own.

Sometimes other medicines are given at the same time.

The safety of this medicine in children under 2 years has not been studied.

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem the same as yours.

Do not use Ondansetron-Claris Solution for Injection to treat any other complaints unless your doctor says to.

Side effects

Check with your doctor or nurse as soon as possible if you think you are experiencing any side effects or allergic reactions due to taking Ondansetron-Claris, even if the problem is not listed below.

Like other medicines, Ondansetron-Claris can cause some side effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

The most commonly reported side effects are:

headache

- a sensation of warmth or flushing
- mild stomach cramps
- constipation or diarrhoea
- dry mouth
- hiccups

These are all mild side effects. There is no immediate reason to stop taking your Injection unless you are concerned.

Tell your doctor or nurse immediately if you notice any of the following:

- wheezy' symptoms
- · chest pain or tightness of the chest
- changes in the way your heart beats, e.g. if you notice it beating faster or slower than normal, or if it beats irregularly or if it 'throbs'
- low blood pressure
- fits or convulsions
- swelling of the eyelids, face, lips, mouth or throat which my cause difficulty in swallowing or breathing
- skin rash, skin lumps or hives
- blurred vision
- dizziness

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

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

If your nausea (feeling of sickness) or vomiting does not go away, ask your doctor what to do.

In certain illnesses and treatments where Ondansetron-Claris has been used, blood vessel blockage has occurred. However, it is important to note that blood vessel blockage has also occurred in these illnesses and treatments when Ondansetron-Claris has NOT been used. Discuss this with your doctor if you have any concerns. If you feel unwell or have any symptoms that you do not understand, you should tell your doctor or nurse immediately. Ondansetron-Claris is not addictive.

Overdose

Because Ondansetron-Claris Solution for Injection can only be given by a health professional, overdose is unlikely to occur. However if you are given too much Ondansetron-Claris you may experience some of the side effects listed above. If you have any concerns ask your doctor or nurse or contact the Poisons Information Centre 13 11 26.

Storage

Store in a cool dry place below 30°C where it is protected from light. Do not leave in a car, on a window sill or in a bathroom.

Keep this medicine where children cannot reach it. A locked cupboard at least one and a half metres off the ground is a good place.

Product description

What it looks like

Ondansetron-Claris Solution for Injection is a clear colourless solution in a glass ampoule.

Other ingredients

Sodium chloride, citric acid, sodium citrate and Water for Injections.

Australian registration numbers:

Ondansetron-Claris 4mg/2mL AUST R 147103

Ondansetron-Claris 8mg/4mL AUST R 155610

Australian Sponsor

Claris Lifesciences Australia Pty Ltd Suite1, Level 1 127-133 Burwood Road Burwood NSW 2134

Distributor

Australia:

AFT Pharmaceuticals Pty Ltd 113 Wicks Road North Ryde NSW 2113 Freephone 1800 097 639

New Zealand:

AFT Pharmaceuticals Ltd Takapuna Auckland 1309 Telephone: (09) 488 0232 Email: customer.service@aftpharm.com Date of preparation: 29 July 2015