

# NOZENTRIX®

8 mg film coated tablets  
Ondansetron

**Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

1. What Nozentrix® tablets are and what they are used for
2. Before you take Nozentrix® tablets
3. How to take Nozentrix® tablets
4. Possible side effects
5. How to store Nozentrix® tablets
6. Contents of the pack and other information

**1. What Nozentrix® tablets are and what they are used for**

Nozentrix® tablets contain a medicine called ondansetron. This belongs to a group of medicines called anti-emetics.

Nozentrix® tablets are used for:

- preventing nausea and vomiting caused by chemotherapy or radiotherapy for cancer
- preventing nausea and/or vomiting after surgery.

Ask your doctor, nurse or pharmacist if you would like any further explanation about these uses.

**2. Before you take Nozentrix® tablets**

**a. Do not take Nozentrix® tablets if:**

- you are taking apomorphine (used to treat Parkinson's disease)
- you are allergic (hypersensitive) to ondansetron or any of the other ingredients in Nozentrix® tablets (listed in Section 6).

If you are not sure, talk to your doctor, nurse or pharmacist before taking Nozentrix® tablets.

**b. Check with your doctor, nurse or pharmacist before taking Nozentrix® tablets if:**

- you have ever had heart problems (e.g. congestive heart failure which causes shortness of breath and swollen ankles)
- you have an uneven heart beat (arrhythmias)
- you are allergic to medicines similar to ondansetron, such as granisetron or palonosetron
- you have liver problems
- you have a blockage in your gut
- you have problems with the levels of salts in your blood, such as potassium, sodium and magnesium.

If you are not sure if any of the above applies to you, talk to your doctor, nurse or pharmacist before taking Nozentrix® tablets.

**c. If you are taking other medicines, herbal or dietary supplements**

Please tell your doctor, nurse or pharmacist if you are taking or have recently taken or might take other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Nozentrix® can affect the way some medicines work. Also some other medicines can affect the way Nozentrix® works.

In particular, tell your doctor, nurse or pharmacist if you are taking any of the following medicines:

- carbamazepine or phenytoin used to treat epilepsy

- rifampicin used to treat infections such as tuberculosis (TB)
- antibiotics such as erythromycin or ketoconazole
- anti-arrhythmic medicines used to treat an uneven heart beat
- beta-blocker medicines used to treat certain heart or eye problems, anxiety or prevent migraines
- tramadol, a pain killer
- medicines that affect the heart (such as haloperidol or methadone)
- cancer medicines (especially anthracyclines and trastuzumab)
- SSRI (selective serotonin reuptake inhibitors) used to treat depression and/or anxiety including fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram
- SNRIs (serotonin noradrenaline reuptake inhibitors) used to treat depression and/or anxiety including venlafaxine, duloxetine.

If you are not sure if any of the above applies to you, talk to your doctor, nurse or pharmacist before having Nozentrix® tablets.

**d. Pregnancy and breast-feeding**

It is not known if Nozentrix® is safe during pregnancy. If you are pregnant, think you are pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking Nozentrix® tablets. Do not breast-feed if you are taking Nozentrix®. This is because small amounts pass into the mother's milk. Ask your doctor or midwife for advice.

**e. Important information about some of the ingredients of Nozentrix® tablets**

This medicine contains lactose. If you have been told by your doctor that you have intolerance to some sugars, speak to your doctor before taking this medicine. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galac-

tose malabsorption should not take this medicine.

**3. How to take Nozentrix® tablets**

Always take Nozentrix® tablets exactly as your doctor has told you. You should check with your doctor, nurse or pharmacist if you are not sure. The dose you have been prescribed will depend on the treatment you are having.

- To prevent nausea and vomiting from highly emetogenic cancer chemotherapy in adults: A single 24 mg dose taken 30 minutes before the start of single-day highly emetogenic chemotherapy.

- To prevent nausea and vomiting from moderately emetogenic cancer chemotherapy in adults:

On the day of chemotherapy:

The usual dose is 8 mg administered 30 minutes before the start of chemotherapy, with a subsequent 8 mg dose 8 hours after the first dose.

On the following 1-2 days:

The usual dose is 8 mg twice a day (every 12 hours) for 1 to 2 days after completion of chemotherapy.

- To prevent nausea and vomiting from moderately emetogenic cancer chemotherapy in children 12 to 17 years of age:

On the day of chemotherapy:

The usual dose is 8 mg administered 30 minutes before the start of chemotherapy, with a subsequent 8 mg dose 8 hours after the first dose.

On the following 1-2 days:

The usual dose is 8 mg twice a day (every 12 hours) for 1 to 2 days after completion of chemotherapy.

- To prevent nausea and vomiting from moderately emetogenic cancer chemotherapy in children 4 to 11 years of age:

On the day of chemotherapy:

The usual dose is 4 mg administered 30 minutes before the start of chemotherapy, with a subsequent 4 mg dose 4 and 8 hours after the first dose.





On the following 1-2 days:

The usual dose is 4 mg three times a day for 1 to 2 days after completion of chemotherapy.

• To prevent nausea and vomiting from radiotherapy in adults:

For total body irradiation:

The usual dose is 8 mg administered 1 to 2 hours before each fraction of radiotherapy each day.

For single high-dose fraction radiotherapy to the abdomen:

The usual dose is 8 mg administered 1 to 2 hours before radiotherapy with subsequent 8 mg doses every 8 hours after the first dose for 1 to 2 days after completion of radiotherapy.

For daily fractionated radiotherapy to the abdomen:

The usual dose is 8 mg administered 1 to 2 hours before radiotherapy, with subsequent 8 mg doses every 8 hours after the first dose for each day radiotherapy is given.

• To prevent nausea and/or vomiting after surgery in adults:

The usual dose is 16 mg administered 1 hour before anesthesia.

Patients with moderate or severe liver problems

The total daily dose should not be more than 8 mg.

Nozentrix® tablets should start to work within one or two hours of taking a dose.

If you are sick (vomit) within one hour of taking a dose

• take the same dose again

• otherwise, do not take more Nozentrix® tablets than the label says.

If you continue to feel sick, tell your doctor or nurse.

**If you take more Nozentrix® tablets than you should**

If you or your child take more Nozentrix® than you should, talk to a doctor or go to a hospital straight away.

Take the medicine pack with you.

**If you forget to take Nozentrix® tablets**

If you miss a dose and feel sick or vomit:

• take Nozentrix® tablets as soon as possible, then

• take your next tablet at the usual time (as shown on the label)

• do not take a double dose to make up for a forgotten dose.

If you miss a dose but do not feel sick

• take the next dose as shown on the label

• do not take a double dose to make up for a forgotten dose.

#### 4. Possible side effects

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

Allergic reactions:

If you have an allergic reaction, stop taking Nozentrix® and see a doctor straight away. The signs may include:

- sudden wheezing and chest pain or chest tightness
- swelling of your eyelids, face, lips, mouth or tongue
- skin rash - red spots or lumps under your skin (hives) anywhere on your body
- collapse.

**Other side effects include:**

**Very common (may affect more than 1 in 10 people)**

• headache.

**Common (may affect up to 1 in 10 people)**

- a feeling of warmth or flushing
- constipation
- changes to liver function test results (if you take Nozentrix® tablets with a medicine called cisplatin, otherwise this side effect is uncommon).

**Uncommon (may affect up to 1 in 100 people)**

- hiccups
- low blood pressure, which can make you feel faint or dizzy

- uneven heart beat
- chest pain
- fits
- unusual body movements or shaking.

**Rare (may affect up to 1 in 1,000 people)**

- feeling dizzy or light headed
- blurred vision
- disturbance in heart rhythm (sometimes causing a sudden loss of consciousness)

**Very rare (may affect up to 1 in 10,000 people)**

- poor vision or temporary loss of eyesight, which usually comes back within 20 minutes.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

#### 5. How to store Nozentrix® tablets

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

- Do not use Nozentrix® tablets after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.
- Store in the original package.
- Do not store Nozentrix® above 30°C.

#### 6. Contents of the pack and other information

**a. What Nozentrix® contains**

Each tablet contains 10 mg of Ondansetron HCl Dihydrate equivalent to 8 mg of free base, as active ingredients.

The other ingredients are: microcrystalline cellulose, lactose monohydrate, pregelatinized Starch, magnesium stearate and yellow opadry.

**b. What Nozentrix® looks like and contents of the pack**

Yellow round biconvex, film coated tablet embossed by the number “42” on one side and plain on the other side.

Nozentrix® is available in packs of 10 tablets.

**To report adverse events, please contact:**

Algorithm S.A.L.

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#### This is a medicament

- A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.

- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold you the medicament.

- The doctor and the pharmacist are experts in medicine, its benefits and risks.

- Do not by yourself interrupt the period of treatment prescribed

- Do not repeat the same prescription without consulting your doctor.

- Keep all medicaments out of reach of children.

Council of Arab Health Ministers  
Union of Arab pharmacists

Marketing Authorisation Holder and Final Batch  
Releaser:

**ALGORITHM S.A.L.** Zouk Mosbeh, Lebanon

Manufacturer:

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