## **Consumer Medicine Information (CMI) summary**

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

## 1. Why am I using EMEXLON?

EMEXLON contains the active ingredient metoclopramide hydrochloride. EMEXLON is used to treat nausea, and vomiting caused by infectious diseases, migraine kidney disease, childbirth, other medications, cancer, or following surgery, chemotherapy or radiation treatment, to activate stomach contractions in conditions where there is a need to encourage normal passage of food through the stomach and intestines.

For more information, see Section 1. Why am I using EMEXLON? in the full CMI.

## 2. What should I know before I use EMEXLON?

Do not use if you have ever had an allergic reaction to EMEXLON or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use EMEXLON? in the full CMI.

## 3. What if I am taking other medicines?

Some medicines may interfere with EMEXLON and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

## 4. How do I use EMEXLON?

- The total daily dosage of metoclopramide hydrochloride (as monohydrate), especially for children and young adults, should not normally exceed 0.5mg/kg bodyweight or 30mg daily.
- Swallow the tablets with a glass full of water.

More instructions can be found in Section 4. How do I use EMEXLON? in the full CMI.

## 5. What should I know while using EMEXLON?

Things you should do	<ul> <li>Remind any doctor, dentist, or pharmacist you visit that you are using EMEXLON.</li> <li>If you are about to be started on any new medicines, remind your doctor and pharmacist that you are taking Emexlon.</li> </ul>	
Things you should not do	<ul> <li>Do not stop using this medicine suddenly.</li> <li>Do not give your medicine to anyone else, even if they have the same condition.</li> </ul>	
Driving or using machines	Be careful driving or operating machinery until you know how Emexlon affects you.     This medicine may cause dizziness, light-headedness, tiredness or drowsiness in some people.	
Drinking alcohol	Be careful when drinking alcohol while you are taking this medicine. If you drink alcohol, it may make you sleepy.	
Looking after your medicine	<ul> <li>Keep your medicine in the pack until it is time to take it. If you take the tablets out of the pack, they may not keep well.</li> <li>Keep your tablets in a cool dry place where the temperature stays below 25°C.</li> </ul>	

For more information, see Section 5. What should I know while using EMEXLON? in the full CMI.

## 6. Are there any side effects?

The common side effects include drowsiness, tiredness, restlessness, dizziness, headache, bowel irregularities, insomnia, anxiety, agitation.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

## **EMEXLON**

Active ingredient(s): metoclopramide hydrochloride

## **Consumer Medicine Information (CMI)**

This leaflet provides important information about using EMEXLON. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using EMEXLON.

#### Where to find information in this leaflet:

- 1. Why am I using EMEXLON?
- 2. What should I know before I use EMEXLON?
- 3. What if I am taking other medicines?
- 4. How do I use EMEXLON?
- What should I know while using EMEXLON?
- 6. Are there any side effects?
- 7. Product details

## 1. Why am I using EMEXLON?

**EMEXLON contains the active ingredient metoclopramide hydrochloride.** EMEXLON is acts by blocking the action of a chemical in the brain which causes nausea and vomiting. It also acts in the stomach and upper intestine to increase muscle contractions.

EMEXLON is used in adults over 20 years to treat nausea, and vomiting caused by infectious diseases, migraine kidney disease, childbirth, other medications, cancer, or following surgery, chemotherapy or radiation treatment, to activate stomach contractions in conditions where there is a need to encourage normal passage of food through the stomach and intestines, with X-rays to help diagnose problems of the stomach and/or intestines, to help with passing tubes into the intestine.

In young adults between 15 15 to 20 years EMEXLON is used to treat severe vomiting of known cause or following chemotherapy or radiation treatment and help with passing tubes.

# 2. What should I know before I use EMEXLON?

#### Warnings

#### Do not use EMEXLON if:

- you are allergic to metoclopramide hydrochloride, or any of the ingredients listed at the end of this leaflet.
- Some of the symptoms of allergic reaction include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, togue or other parts of the body, rash, itching or hives on the skin..
- Always check the ingredients to make sure you can use this medicine.

- Active bleeding from the stomach and/or digestive tract.
- Blockage of the stomach and/or digestive tract
- Recent surgery of the stomach and/or digestive tract
- pheochromocytoma (an adrenaline-producing tumour of the adrenal gland)
- epilepsy (fits or seizures)
- take other medication such as antipsychotic/neuroleptic medication and certain antidepressants that can cause movement disorders (extrapyramidal reactions).

#### Check with your doctor if you:

- have any other medical condition like Parkinson's disease, liver or kidney problem, high blood pressure, asthma.
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

## Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

## 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

## Some medicines may interfere with EMEXLON and affect how it works.

- Tranquilizers or anti-anxiety medications
- Strong pain killers (e.g., codeine or morphine)
- Sedatives or sleeping medication.
- Atropine-like medication (e.g., some cold preparations, travel sickness medicines)
- Tetracycline antibiotics, paracetamol, levodopa
- digoxin

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect EMEXLON.

#### 4. How do I use EMEXLON?

#### How much to take / use

- The dose of Emexlon varies with the age of the patient and with the reason for use.
- The total daily dosage of metoclopramide hydrochloride (as monohydrate), especially for children and young adults, should not normally exceed 0.5mg/kg bodyweight or 30mg daily.
- Space the doses as evenly as possible throughout the day.
- Tablets:

20 years and over – One tablet (10mg) every 8 hours 15-20 years –  $\frac{1}{2}$  to 1 tablet (5mg to 10mg) every 8 hours

Swallow the tablets with a glass full of water The tablets can be broken in half (along the break line) Do not exceed the prescribed dose.

### When to take / use EMEXLON

- EMEXLON should be used at about the same time each day. Taking it at the same time each day will have the best effect. It will also help you remember when to take it.
- Take the medicine 30 minutes before meals.
- Continue taking the medicine for as long as your doctor tells you.

## If you forget to use EMEXLON

EMEXLON should be used regularly at the same time each day. Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

If you miss your dose at the usual time, take it as soon as you remember it, and then go back to taking this medicine as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed. This may increase the chance of getting unwanted side effects.

If you are not sure what to do, ask your doctor of pharmacist.

If you have trouble remembering your medicine

#### If you use too much EMEXLON

If you think that you have used too much [medicine name], you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

# 5. What should I know while using EMEXLON?

#### Things you should do

#### Call your doctor straight away if you:

- If vomiting or nausea persists, tell your doctor
- If you are about to be started on any new medicines, remind your doctor and pharmacist that you are taking Emexlon.
- Tell any other doctor, dentists, and pharmacists who treat you hat you are taking this medicine.
- If you are going to have surgery, tell the surgeons or anesthetists that you are taking this medicine. It may affect other medicines used during surgery.
- If you become pregnant while taking this medicine, tell your doctor immediately.

Remind any doctor, dentist or pharmacist you visit that you are using EMEXLON.

#### Things you should not do

- Do not stop use EMEXLON to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, eveN if they have the same condition.

#### **Driving or using machines**

Be careful before you drive or use any machines or tools until you know how EMEXLON affects you.

Be careful driving or operating machinery until you know how Emexlon affects you. This medicine may cause dizziness, light-headedness, tiredness or drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous. Children should be careful when riding bicycles or climbing trees.

#### **Drinking alcohol**

#### Tell your doctor if you drink alcohol.

Be careful when drinking alcohol while you are taking this medicine. If you drink alcohol, it may make you sleepy.

#### Looking after your medicine

- Keep your medicine in the pack until it is time to take it. If you take the tablets out of the pack, they may not keep well.
- Keep your tablets in a cool dry place where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

#### When to discard your medicine (as relevant)

[Include any specific information about discarding the medicine, e.g. 28 day expiry from date of first use].

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

## Less serious side effects

Less serious side effects	What to do
<ul> <li>Drowsiness, tiredness</li> <li>Restlessness</li> <li>Dizziness, headache</li> <li>Bowel irregularities</li> <li>Insomnia</li> <li>Anxiety</li> <li>Agitation</li> </ul>	Speak to your doctor if you have any of these less serious side effects and they worry you.

#### Serious side effects

Serious side effects	What to do
<ul> <li>uncontrolled or repeated movements - e.g. sucking or smacking of the lips, darting of the tongue, chewing movements, uncontrolled movements of the arms or legs. This may be a sign of tardive dyskinesia, a movement disorder which potentially can be irreversible.</li> <li>Fast heartbeat</li> <li>Depression</li> <li>Swelling of hands, ankles, or feet</li> <li>allergic reaction including fainting, swelling of limbs, face, lips, mouth, or throat which may cause difficulty swallowing or breathing.</li> <li>sudden uncontrolled muscle spasm, stiffness of the arms or legs, muscle spasm of the face, locked-jaw or upturned eyes.</li> </ul>	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

- shuffling walk, slowing of all movement, muscle tremor
- neuroleptic malignant syndrome, a serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <a href="https://www.tga.gov.au/reporting-problems">www.tga.gov.au/reporting-problems</a>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

#### 7. Product details

This medicine is only available with a doctor's prescription.

#### What EMEXLON contains

Active ingredient (main ingredient)	Metoclopramide Hydrochloride (as monohydrate)
Other ingredients	Maize starch
(inactive ingredients)	<ul> <li>Pregelatinised maize starch</li> </ul>
	Microcrystalline cellulose
	<ul> <li>Colloidal anhydrous silica</li> </ul>
	•Stearic acid
	<ul> <li>Hypromellose</li> </ul>
	Macrogol 6000
	•Titanium dioxide
	•Purified talc
Potential allergens	N/A

Emexion tablets do not contain sucrose, gluten, tartrazine or any other azo dyes.

Do not take this medicine if you are allergic to any of these ingredients.

#### What EMEXLON looks like

EMEXLON tablets are white to off-white, circular, biconvex, film-coated tablets with a break line on both sides.

Emexlon tablets are available in a blister pack of 25 tablets or a bottle of 100 tablets.

Emexlon 10 mg blister pack – AUST R 229659

Emexlon 10 mg bottle – AUST R 268301

#### Who distributes EMEXLON

Arrotex Pharmaceuticals Pty Ltd 15-17 Chapel Street Cremorne VIC 3121 Australia

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