

PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

**Pylera 140 mg/125 mg/125 mg
capsules bismuth subcitrate
potassium metronidazole
tetracycline
hydrochloride**

Read all of this leaflet carefully before you start taking Pylera because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. WHAT PYLERA IS AND WHAT IT IS USED FOR

Pylera contains 3 different active ingredients: bismuth subcitrate potassium, metronidazole and tetracycline hydrochloride. Tetracycline and metronidazole belong to a group of medicines called antibiotics. Bismuth subcitrate potassium helps the antibiotics treat the infection.

Pylera contains a group of medicines used to treat adult patients infected with *Helicobacter pylori* (*H. pylori*) who have or have had an ulcer. *H. pylori* is a bacteria found in the stomach lining.

Pylera should be taken together with a medicine called omeprazole. Omeprazole is a medicine that works by reducing the amount of acid that your stomach produces. Pylera, taken with omeprazole works together to treat the infection and reduce the inflammation of the stomach lining.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE

PYLERA Do not take Pylera

- if you are **pregnant or breast-feeding**
- if you are less than **12 years** of age
- if you suffer from **kidney problems**
- if you suffer from **liver problems**
- if you are **allergic (hypersensitive)** to bismuth subcitrate potassium, metronidazole or other nitroimidazole derivatives, tetracycline or any of the other ingredients in Pylera (listed in section 6)
- If you have Cockayne syndrome (see Warnings and precautions)

Warnings and precautions

Talk to your doctor or pharmacist before taking Pylera.

Cases of severe irreversible liver toxicity/acute liver failure, including cases with fatal outcomes with very rapid onset after initiation of systemic use of metronidazole, have been reported in patients with Cockayne Syndrome.

Tell your doctor immediately and stop taking metronidazole if you develop:

- Stomach pain, anorexia, nausea, vomiting, fever, malaise, fatigue, jaundice, dark urine, putty or mastic coloured stools or itching.

Metronidazole, one content of this medicine, can booster changes on the ECG, that is a prolongation of the QT-interval, resulting in delayed conduction of electrical signals and heart rate abnormalities (arrhythmia), when given with compounds that can induce similar changes to the ECG. Talk to your doctor before taking Pylera, especially if you have previously experienced such ECG changes or arrhythmias (see “other medicines and Pylera”).

Take special care with Pylera

- if you have to go for an x-ray as Pylera may affect the results of x-rays
- if you go for blood tests, as Pylera may affect the results of your blood tests
- if you have been told by your doctor that you have an intolerance to some sugars

Avoid the sun and using sun beds during treatment with Pylera as it can exaggerate the effects of the sun. Tell your doctor if you get sun burnt.

Children and adolescents

Pylera capsules must not be given to children below the age of 12 and are not recommended in children 12 to 18 years of age.

Other medicines and Pylera

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This includes medicines that you buy without a prescription.

In particular tell your doctor if you are taking or have recently taken any of the following medicines:

- lithium used to treat some mental illness
- medicines used to thin the blood or which prevent blood clotting (e.g. warfarin)
- phenytoin and phenobarbital for epilepsy
- methoxyflurane (an anaesthetic)
- other antibiotics, particularly penicillin
- supplements containing iron, zinc, sodium bicarbonate
- the combination of Pylera with other drugs that contain bismuth, used long term, may affect the nervous system
- busulfan and fluorouracil used for chemotherapy
- cyclosporin used to lower your body's immune reaction after transplants
- disulfiram used to treat people with drinking problems
- ranitidine used for indigestion and heartburn
- retinoids for skin disorders
- atovaquone to treat an infection of the lung
 - medicines known to cause changes to the ECG (prolongation of the QT interval) and for which an increase in blood concentrations is caused by metronidazole. Examples of such substances include:
 - Amiodarone (used to treat heart rate abnormalities);
 - Ondansetron (used to treat nausea and vomiting);

- Methadone (used as substitution therapy in opioid dependence);
- Domperidone (used to treat nausea and vomiting)

Do not take antacids containing aluminium, calcium or magnesium at the same time as Pylera.

Pylera with food, drink and alcohol

Take Pylera with a full glass of water (250 ml) **after** meals and at bedtime (preferably after a snack).

Do not eat or drink any **dairy products** (such as milk or yoghurt) or drinks with added **calcium**, at the same time as Pylera capsules and throughout your treatment with Pylera, as they may affect the way Pylera works.

Do not drink any **alcohol** while taking Pylera and for at least 24 hours after finishing your treatment. Drinking alcohol when taking Pylera may cause unpleasant side effects, such as feeling sick (nausea), being sick (vomiting), stomach pain (abdominal cramps), hot flushes and headaches.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Do not take Pylera if you are pregnant, might become pregnant during treatment or think you may be pregnant. Speak to your doctor if you become pregnant while taking Pylera.

Do not breast-feed while you are taking Pylera. This is because small amounts of the components of Pylera may pass into the breast milk.

Driving and using machines

Do not drive or use any tools or machines if you feel dizzy, sleepy, have fits (convulsions) or experience temporary blurred or double vision.

Pylera contains lactose and potassium

Pylera contains lactose, which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Pylera contains approximately 96 mg of potassium per dose (3 capsules containing 32 mg of potassium each). To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

3. HOW TO TAKE PYLERA

Always take this medicine exactly as your doctor has told you. Pylera should be taken together with a medicine called omeprazole. Check with your doctor or pharmacist if you are not sure.

Adults and the elderly

Do not open capsules and swallow capsules whole.

Take 3 Pylera capsules after breakfast, 3 capsules after lunch, 3 capsules after your evening meal and 3 capsules at bedtime (preferably after a snack), a total of 12 capsules per day. Swallow the capsules whole while seated with a full glass (250 ml) of water to avoid any irritation to the throat. Do not immediately lay down after Pylera intake. It is important to finish the complete course of treatment (10 days) and to take all 120 capsules.

Take one omeprazole 20 mg capsule/tablet with the breakfast and evening doses of Pylera (total of 2 omeprazole capsules/tablets per day).

Daily dosing schedule for Pylera

Time of dose	Number of capsules of Pylera	Number of capsules/tablets of omeprazole
After breakfast	3	1
After lunch	3	0
After evening meal	3	1
At bedtime (preferably after a snack)	3	0

If you take more Pylera than you should

If you take more than the recommended dose of Pylera per day, then you should tell your doctor or go to your nearest hospital emergency department. Take the bottle and any remaining capsules with you. This is so that the doctor knows what you have taken.

If you forget to take Pylera

If you forget to take Pylera, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose. If you miss more than 4 consecutive doses of Pylera (1 day), contact your doctor.

If you stop taking Pylera

It is important that you finish the full course of treatment even if you begin to feel better after a few days. If you stop taking Pylera too soon, your infection may not be completely cured and the symptoms of the infection may return or get worse. You might also develop resistance to tetracycline and/or metronidazole (antibiotics).

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Pylera and contact a doctor or go to a hospital immediately if you develop or notice any of the following:

- swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing.
- an itchy, lumpy rash (hives) or nettle rash (urticaria). These could be signs of an allergic reaction.
- Severe skin reactions (Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell syndrome), Drug reaction with Eosinophilia and Systemic Symptoms (DRESS)) (See below “Not Known” side effects).

A serious but very rare side effect is a brain disease (encephalopathy). Symptoms vary but you might get a fever, stiff neck, headache, see or hear things that aren't there. You might also have problems using your arms and legs, problems with speaking or feel confused. Talk to your doctor straight away if you notice these side effects.

Other possible side effects

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

- changes in consistency or colour of your faeces including dark coloured faeces (black stools)
- diarrhoea
- nausea
- bad or metallic-taste

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

- abdominal pain

- constipation
- dry mouth
- vomiting
- passing wind /abdominal gas
- headache
- feeling weak
- feeling low in energy or tired
- feeling generally unwell
- vaginal infection – symptoms include itching and irritation in the genital area, burning sensation or yellowish / white vaginal discharge
- blood tests may show increased levels of liver enzymes (transaminases)
- dark-coloured urine
- loss or decreased appetite
- feeling dizzy / light-headed feeling
- feeling sleepy
- skin problems such as redness (rash)

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

- allergic reaction to the drug (symptoms include swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing, or an itchy, lumpy rash (hives) or nettle rash (urticaria))
- feeling bloated / swollen abdomen
- burping or belching
- open sore inside the mouth / mouth ulcers
- changes in the colour of your tongue (dark tongue)
- swollen tongue
- chest pain, chest discomfort
- yeast (candida) infections, which can occur in the mouth (symptoms include white spots in the mouth) or in the genitals (symptoms including severe itching, burning sensation, soreness)
- numbness
- tingling / pins and needles
- trembling
- feeling anxious, depressed or difficulty sleeping
- memory disturbance
- skin problems such as itching or hives (urticaria)
- blurred (hazy) vision
- vertigo (head spinning)

Not Known (cannot be estimated from the available data):

- Serious illness with blistering of the skin, mouth, eyes and genitals (Steven-Johnson syndrome)
- Serious illness with blistering of the skin (Lyell syndrome, Toxic epidermal necrolysis)
- Flu-like symptoms, rash on the face then extended rash with a high temperature, increased levels of liver enzymes seen in blood tests, increase in a type of white blood cell (eosinophilia), enlarged lymph nodes (DRESS)
- Blistering (bubbles on the skin) and exfoliation of the skin (skin peeling)
- Aseptic meningitis: A group of symptoms together including: fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light. This may be caused by an inflammation of the membranes that cover the brain and spinal cord (meningitis).
- Nerve damage which may cause numbness, tingling, pain or a feeling of weakness in the arms or legs (Peripheral neuropathy)
- Inflammation of the large intestine (Pseudomembranous colitis)
- Neurological disorder called cerebellar syndrome, which symptoms can include difficulties in coordinating movements, speaking and/or walking, involuntary movement of the eyes, and

shaking. It may resolve upon stopping the treatment.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE PYLERA

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

Do not use this medicine after the expiry date which is stated on the carton and bottle after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions. Store in the original package in order to protect from light and moisture.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER

INFORMATION

What Pylera contains

The active substances are bismuth subcitrate potassium, metronidazole and tetracycline hydrochloride. Each capsule contains 140 mg of bismuth subcitrate potassium (equivalent to 40 mg bismuth oxide), 125 mg of metronidazole and 125 mg of tetracycline hydrochloride.

The other ingredients are: magnesium stearate (E572), lactose monohydrate, talc (E553b), titanium dioxide (E171), gelatin and printing ink containing shellac, propylene glycol and red iron oxide (E172).

This medicine contains lactose and potassium. See section 2.

What Pylera looks like and contents of the pack

Pylera capsules are elongated, white, opaque hard capsules with 'BMT' printed on the cap in red. They contain a white powder plus a smaller white, opaque capsule containing a yellow powder.

Pylera capsules are available in high density polyethylene bottles of 120 capsules.

A desiccant (silicon pack) and rayon coil are included in the bottle to help keep your medicine dry. Do not eat the desiccant or rayon coil.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

LABORATOIRES JUVISE PHARMACEUTICALS

149 Boulevard Bataille de Stalingrad

69100 Villeurbanne

France

Manufacturer

SKYEPHARMA PRODUCTION SAS
Zone Industrielle Chesnes Ouest,
55 rue du Montmurier,
38070 Saint Quentin Fallavier,
France

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium, Luxembourg: Tryplera

Austria, Bulgaria, Czech Republic, Denmark, Estonia, Germany, Greece, France, Hungary, Ireland, Italy, Finland, Latvia, Lithuania, Malta, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Romania: Pylera

Netherlands: <Name of the medicinal product>

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