IMPORTANT INFORMATION FOR HEALTHCARE PROFESSIONALS AND PATIENTS
CAUTION IN USE NOTIFICATION

To: Pharmacists

Supply of Tranylcypromine 10mg Tablet-UK – PL 12762/0075 Batch No. F0003, Expiry date: February 2023 to the Ireland Market

I am writing to you in connection with the supply of the above referenced product, Tranylcypromine 10mg Tablets- PL 12762/0075. We are unable to supply Irish licensed packs (Parnate 10mg Coated Tablets) at the moment and have obtained approval from the HPRA to supply the corresponding product from the UK market to fulfil the urgent medical need for the product. These packs are labelled with Tranylcypromine 10mg Tablets- PL 12762/0075, Batch No. F0003, with an expiry date of February 2023.

The pharmaceutical composition and manufacturing practices followed for the product are the same, but there are minor differences in the representation of the product, PIL and carton artwork for both countries. Please refer below table for more details.

Some healthcare professionals may note the above differences and may bring these to your attention. If this happens, please explain that the pack they have received is United Kingdom stock (Batch Number: F0003) and that it has been approved by the HPRA for use in Ireland as a temporary measure.

Ireland-Parnate sugar coated Carton and Label	**Track changes are differences in UK-Tranylcypromine sugar coated Carton and Label.**
NAME OF THE MEDICINAL PRODUCT	**1. NAME OF THE MEDICINAL PRODUCT**
Parnate® 10mg Coated tablets Tranylcypromine	~~Parnate® 10mg Coated tablets~~ Tranylcypromine 10mg Tablets
2. MARKETING AUTHORISATION NUMBER(S)	**2. MARKETING AUTHORISATION NUMBER(S)**
PA1142/035/001	PL 12762/0075 ~~PA1142/035/001~~
3. INFORMATION IN BRAILLE	**3. INFORMATION IN BRAILLE**
Carton only PARNATE #10 MG COATED TABLETS	Carton only ~~PARNATE~~ ~~#10 MG~~ ~~COATED~~ ~~TABLETS~~ TRANYLCYPROMINE 10 MG TABLETS

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The indications, posology, contraindications, warnings, adverse reactions mentioned in the Patient Information Leaflet (PIL) for the approved product i.e., Parnate and Tranylcypromine 10 mg Tablet in Ireland and United Kingdom is similar. Thus, the safety profile of Tranylcypromine 10 mg Tablet in United Kingdom is similar to that of product registered in Ireland, hence there would be no impact on patient safety.

For further details on the product, please refer to the attached approved Irish package leaflet appended to this letter for your information.

For further details on the product, please refer to the approved Irish summary of product characteristics (SmPC) and package leaflet, which are available on the HPRA website: www.hpra.ie.

The CIU letter is also published on the HPRA web site (link).

Please ensure all relevant staff <*and patients*> are made aware of the content of this letter and that the information is communicated to the patients.

If you have any questions, please contact:
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Yours faithfully,

Harleen

Dr. Harleen Bindra

Date: 04-Nov-2022

Package leaflet: Information for the patient
PARNATE® 10MG COATED TABLETS
Tranylcypromine

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet (See section 4).

What is in this leaflet

1. WHAT PARNATE TABLETS ARE AND WHAT THEY ARE USED FOR

Parnate 10mg Coated Tablets will be referred to as Parnate or Parnate Tablets throughout this leaflet.

Parnate Tablets contain the active substance called tranylcypromine which belongs to a group of antidepressant medicines known as monoamine oxidase inhibitors (MAOIs). It works by stopping the breakdown of two substances in the brain called serotonin and noradrenaline. Your medicine should help bring these substances back to normal levels.

Parnate tablets are used to treat moderate to severe depression in adults. These tablets are not suitable for use in situations which make someone feel slightly depressed or apprehensive. It can also help you if you are having feelings of fear (phobia) which sometimes occurs in depression. This medicine is often used when other types of antidepressant medicines have not worked.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PARNATE

Do not take Parnate if

- you are allergic to tranylcypromine or any of the other ingredients of Parnate (listed in section 6)
- you are taking other MAOIs or have taken other MAOIs within the last two weeks
- you have taken clomipramine or imipramine within the last three weeks or are planning to take them within the next three weeks
- you suffer from porphyria which is an inherited disease affecting the nervous system and skin
- you have severe heart disease or any disease of the blood vessels of the brain
- you have pheochromocytoma which is a tumour of the adrenal glands (glands near the kidneys) causing high blood pressure
- you have been diagnosed with an overactive thyroid gland (a gland in the neck)
- you have problems with your liver or a disorder affecting the blood cells (your doctor will know)
- you are taking any of the medicines listed under “Do not take” in the “Other Medicines and Parnate”.

Please tell your doctor if any of the above apply to you, and do not take Parnate.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine if you:
- are elderly
- have cardiovascular disease (also known as heart disease)
- suffer from seizures/fits (epilepsy)
- have a history of dependence on drugs or alcohol
- are taking any of the medicines listed under: "Other Medicines and Parnate" section of this leaflet

Even though some of the above may be obvious, it is important that your doctor is aware if any of them apply to you.

Thoughts of suicide and worsening of your depression or anxiety disorder:
If you are depressed and/or have anxiety disorders, you can sometimes have thoughts of harming or killing yourself (see section 4 'Possible side effects'). These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think like this if you:
• have previously had thoughts about killing or harming yourself
• are a young adult. Information from clinical trials have shown an increased risk of suicidal behavior in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself, at any time, *contact your doctor or go to a hospital straight away*. You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behavior.

Children and adolescents
Parnate is not recommended for children under 18 years old (see section 3 'Use in children and adolescents').

Other medicines and Parnate
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

DO NOT take Parnate with the following medicines
- medicines called sympathomimetic agents - these include ephedrine, pseudoephedrine, adrenaline and noradrenaline (these may be found in medicines used to treat heart problems and asthma as well as some decongestants and cough/cold remedies)
- bupropion, a medicine to help you stop smoking
- medicines to control appetite, e.g. amphetamine and fenfluramine
- medicines that treat Parkinson's disease, e.g. levodopa
- dopamine, a medicine used to treat certain heart conditions
- the pain killers pethidine and nefopam
- general anaesthetics such as propofol, which are used in surgery
- other medicines used to treat depression (e.g. amitriptyline, imipramine, tryptophan)
- buspirone, used to treat anxiety
- metrizamide, used as a nonionic radiopaque contrast agent.

Parnate Tablets must be taken with caution if you are taking the following medicines
• other MAOIs such as Isocarboxazid
• strong pain killers e.g. codeine
• medicines to treat seizures/fits, e.g. carbamazepine
• barbiturates used to treat severe sleeping problems, e.g. amylobarbitone
• SSRIs such as fluoxetine or sertraline (for depression). Taking your medicine with these products may cause the following serious side effects: sweating, extreme agitation, confusion, muscle stiffness
• medicines for high blood pressure (e.g. guanethidine, reserpine, methyldopa)
• medicines to treat diabetes (e.g. insulin, metformin)
• antihistamines used to treat allergies, e.g. cetirizine.

Parnate Tablets with food, drink and alcohol
You should NOT take alcohol (especially red wine) whilst you are taking Parnate Tablets. This includes non-alcoholic beer, lager or wine.

Parnate Tablets stops the breakdown of a substance called tyramine which is found in large amounts of certain foods. If this substance is not broken down, it can cause very high blood pressure (hypertensive crisis). See section 4 - Possible side effects of this leaflet. So, whilst you are taking Parnate Tablets, you should avoid the following foods:
• cheese – cooked or plain (e.g. cheddar or processed cheese made from mature cheese)
• yeast extracts (e.g. Bovril, Oxo, Marmite, brewer's yeast)
• meat, fish or poultry which is not fresh or has been pickled or aged e.g. hung game, pickled herrings
• broad bean pods
• banana skins.

Once you stop taking Parnate Tablets, your doctor will tell you when you can start to eat these foods again.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Parnate should NOT be used during pregnancy or breastfeeding unless your doctor thinks it is essential.
This medicine may pass into breast milk.
Your doctor will decide whether you should ablactate (gradually reduce) or stop therapy with Tranylcypromine. Effects of Tranylcypromine on fertility are unknown.

Driving and using machines
Do not drive or use machines when you first start to take this medicine as it may make you feel drowsy or dizzy, or affect your concentration. Wait until you are certain that you are not getting these side effects. If in any doubt, speak to your doctor before you drive or use machines.

Parnate 10mg Tablets contains
• Ponceau 4R (E124): which may cause allergic reactions. • Sucrose: If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. HOW TO TAKE PARNATE TABLETS

Always take this medicine exactly as your doctor or pharmacist has told you. Do **NOT** take more than your doctor tells you to.

Check with your doctor or pharmacist if you are not sure.

Swallow the tablets whole with a glass of water.

The recommended dose for adults is:
• one 10mg tablet in the morning and one 10mg tablet in the afternoon each day. Try to take the last dose before 3 o'clock in the afternoon
• this dose may be increased by your doctor to three tablets a day. Take the extra tablet at mid-day
• if you are elderly, your doctor will usually prescribe you a lower dose.

When you start to feel better, your doctor may change your dose to one 10mg tablet a day. Do NOT take more than three tablets each day unless your doctor tells you to. Your doctor will probably check your blood pressure while you are taking Parnate Tablets.

Use in children and adolescents:
Parnate Tablets are not recommended for children under 18 years of age. (see section 2 'Children and adolescents').

If you take more Parnate Tablets than you should
If you think that you, or any other person, have taken too many tablets, contact your doctor or hospital casualty department immediately. Take any remaining tablets and this leaflet with you so that the medical staff know exactly what you have taken.

If you forget to take Parnate tablets
If you miss a dose, wait until your next dose. Do not take the dose you have missed. You can then carry on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Parnate tablets
Continue to take Parnate even if you no longer feel ill. DO NOT STOP taking this medicine without talking with your doctor first, especially if you have taken large doses for a long time.
When the time comes to stop, your doctor will probably decrease your dose gradually as stopping the tablets suddenly may cause ill-effects such as nausea (feeling sick), vomiting (being sick), feeling unwell vivid nightmares, fits, loss of contact with reality, usually including false beliefs about what is taking place or who one is (delusions) and seeing or hearing things that aren't there (hallucinations). Symptoms will usually start 24 to up 72 hours after you stop taking this medicine abruptly (see section 4 possible side effects).

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.

- if you eat foods or take medicines which interact with the active ingredient tranylcypromine, you may get very high blood pressure (a hypertensive crisis).

If you notice any of the following symptoms please see your doctor immediately:

- frequent or throbbing headaches, painful or stiff neck, changes in heart rate, pain in the middle of the chest, feeling sick or being sick, sweating, paleness, or flushing of the skin and enlarged pupils which may make bright sunlight uncomfortable. Although very rare, there may be muscle weakness or paralysis (loss of movement) down one side of the body and there have been a few deaths from hypertensive crisis
- thoughts of suicide and suicidal behaviour early on in treatment or shortly after stopping treatment (see section 2 'Thoughts of suicide and worsening of your depression or anxiety disorder')
- sometimes patients feel anxious whilst taking this medicine and rarely some patients will become very agitated or irritable. Your doctor may reduce your dose if this happens
- some patients get low blood pressure and may feel dizzy on standing up. If this continues for a long time, your doctor may stop your medicine.
- Liver problems (symptoms include yellowing of the skin and the whites of the eyes), bruising and changes in blood have been reported. Therefore, if you get a bad sore throat or high fever or become very tired and pale or notice bruises and nose bleeds, tell your doctor.

Other side effects which may occur include:

Rare: may affect up to 1 in 1,000 people

- soreness in the hands and feet, which may be a sign of inflamed nerves
- A need to take increasingly higher doses to obtain the same effect (tolerance)
- seeing or hearing things that are not real (hallucinations)
- elated moods and excitability (hypomania)
- drug dependence (addiction)

Not known: frequency cannot be estimated from the available data

- difficulty in sleeping, mild headache, sleepiness, weakness, dizziness, fast heart beat (palpitations), restlessness, dry mouth, diarrhoea, vomiting (being sick), blurred vision, nausea (feeling sick), feeling of tiredness, water retention or swelling, weight gain, increased appetite, rash and difficulty in passing water.

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

Do not use Parnate Tablets after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.

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Do not store above 25°C. Keep the container in the outer carton in order to protect from light and tightly closed in order to protect from moisture.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Parnate Tablets contain

The active substance is tranylcypromine (as tranylcypromine sulfate). Each coated tablet contains 10mg of the active substance.
The other ingredients are sucrose, maize starch, calcium sulfate dihydrate (E516), carmellose sodium, magnesium stearate (E470b). The coating contains gelatin, sucrose, docusate sodium, purified talc (E553b), light kaolin (E559), calcium carbonate (E170), ethylcellulose, acacia (E414), ponceau 4R (E124), maize starch, titanium dioxide (E171) & carnauba wax (E903).

What Parnate Tablets look like and contents of the pack

Parnate are geranium red coloured, bi-convex, sugar-coated tablets.
They are packed in plastic containers with 28 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder

Amdipharm Limited,
Temple Chambers, 3 Burlington Road,
Dublin 4, Ireland

Manufacturer

Dales Pharmaceuticals Ltd.,
Snaygill Industrial Estate,
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