PACKAGE LEAFLET

Package leaflet: Information for the user

Phenelzine 15 mg film-coated tablets
phenelzine sulfate

Warning – Thoughts of self-harm and suicidal behaviour – see section 2

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Please 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 signs of illness are the same as yours.
- If you suffer from 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 Phenelzine is and what it is used for
2. What you need to know before you take Phenelzine
3. How to take Phenelzine
4. Possible side effects
5. How to store Phenelzine
6. Contents of the pack and other information

1. What Phenelzine is and what it is used for

The full name of your medicine is Phenelzine 15 mg film-coated tablets. It is referred to as Phenelzine throughout this leaflet.

Phenelzine contains the active ingredient phenelzine sulfate, which belongs to a group of medicines called monoamine oxidase inhibitors, or MAOIs.

Phenelzine is used to treat certain types of depression. It works by changing the way messages are sent from one nerve to another in the brain. As with many other kinds of medications and treatments, we don't know for certain how antidepressants work. We do know that they affect the activity of certain chemicals in our brains. These are called neurotransmitters, and pass signals from one brain cell to another. The neurotransmitters most affected by antidepressants are serotonin and noradrenaline. However, research suggests that antidepressants work on the brain in multiple ways that go beyond simple chemical reactions. This research suggests that they:
- influence how the body responds to stress
- improve our negative thinking
- stop or even reverse damage to brain cells

Phenelzine is especially helpful when:
- depression does not follow the typical pattern
- anxiety or fear is a main symptom
- treatment with other antidepressants has failed

2. What you need to know before you take Phenelzine

Do not take Phenelzine
- if you are allergic to phenelzine or any of the other ingredients of this medicine (listed in section 6)
- if you have a growth on the adrenal glands near your kidneys which is causing high blood pressure (phaeochromocytoma)

- if you have liver disease – now or in the past
- if you have a disease affecting blood supply to your brain, such as stroke
- if you have heart disease
- if you are in a manic phase
- if you are pregnant or breast-feeding
- if you are below 16 years of age
- if you are going to have surgery or major dentistry
- if you are already taking, or have recently stopped, other antidepressants i.e. MAOIs, tricyclics, Selective Serotonin Re-uptake Inhibitors (SSRI) or Serotonin Noradrenaline Re-uptake Inhibitors (SNRI)
- if you are taking strong pain killers, such as morphine or pethidine
- if you are taking guanethidine (used to treat high blood pressure), dextromethorphan (used in cough and cold medicines), medicines which affect the central nervous system and make you feel sleepy or medicine used to treat migraines.

If any of these apply to you, tell your doctor or pharmacist before taking Phenelzine. It is important to wait between using certain medicines and starting Phenelzine, read section 2 "Other medicines and Phenelzine" carefully.

Warnings and precautions
Talk to your doctor or pharmacist before taking Phenelzine
- if you have agitation
- if you have epilepsy
- if you have porphyria (which may make the skin sensitive to sunlight, or may affect the nervous system, causing abdominal pain, vomiting, muscle weakness, fits and mental disturbances)
- if you have abnormalities of blood cells, this could be caused by many different diseases and symptoms can include bleeding problems, weakness or pale skin colour, or frequent infections
- if you have diabetes mellitus
- if you have schizophrenia
- if you have manic depression
- if you are taking diuretics (water tablets)
- if you are undergoing ECT (electroshock treatment)
- if you are going to have surgery or major dentistry: tell your doctor or dentist because Phenelzine may interact with certain anaesthetics and should not be taken for two weeks before surgery.

Your blood pressure should be monitored frequently by your doctor and Phenelzine should be stopped if palpitations or frequent headaches occur.

Thoughts of suicide and worsening of your depression or anxiety disorder
This medicine may be associated with thoughts of self-harm and suicidal behaviour in some people. Tell someone you trust, who can help you in an emergency, that you are taking this medicine and ask that they read this leaflet.
Talk to your trusted person, prescriber or go to a hospital straight away, if after starting this medicine, you have new or worse:
- Feelings of anxiety or irritability
- Feelings of restlessness and agitation
- Extreme increases in activity and difficulty sleeping
- Thoughts of acting on dangerous impulses to harm yourself
- Thoughts about suicide or dying
- Changes in behaviour or mood you, or someone you trust, notices and is worried about

In some people, thoughts of self-harm and suicidal behaviour may be increased when first starting antidepressants. Antidepressants take time to work; and sometimes side effects occur before you or others notice improvements in your mood.

Never stop taking an antidepressant suddenly without first talking to a healthcare professional. Stopping an antidepressant medicine suddenly can cause other symptoms related to withdrawal to occur.

Information from clinical trials has shown the highest risk of thoughts of self harm and suicidal behaviour, is in adults aged less than 25 years who were treated with an antidepressant but the risk applies to people of all ages treated with these medicines.

Call NHS 111 who can offer you support, until you can be with someone who can help you in person.

Other medicines and Phenelzine
Please tell your doctor, dentist or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor if you are taking any of the following medicines, because Phenelzine may interact with them:

- cough and cold cures, cough medicines
- hay fever medications, asthma inhalant medications
- appetite-suppressing medicines, weight-reducing preparations and 'pep' pills
- strong pain killers (pethidine and morphine). This could be a serious reaction
- tryptophan, amphetamines and medicines of the type known as sympathomimetic amines (adrenaline, epinephrine, fenfluramine, ephedrine, phenylpropanolamine, dopamine and levodopa). Some of these may be in medicines bought without a prescription.
- medicines used to treat high blood pressure (particularly guanethidine)
- diabetes medications
- antimuscarinic medicines, used to treat motion sickness, muscle cramps in the gut or bladder, or Parkinson's disease
- anti-emetic medicines known as 5-HT3 antagonists which help to stop you feeling or being sick
- medicines which make you sleepy (including barbiturates and alcohol) and local anaesthetics including cocaine. The effect of these medicines may be increased by Phenelzine
- amfebutamone (to help you give up smoking). This should not be taken at the same time as, or within 14 days of, Phenelzine
- migraine medications known as 5-HT1 agonists or pizotifen. These should not be taken at the same time as, or within 14 days of, Phenelzine
- medicines to treat epilepsy, altretamine (for ovarian cancer), doxapram (to stimulate breathing in emergency situations), tetrabenazine (for Huntington's chorea), oxypertine and clozapine (for schizophrenia and other similar illnesses), methylthioninium chloride (an antidote treat problems with your blood resulting from exposure to some medicines or chemicals that can cause a disease called methaemoglobinaemia)
- other antidepressants:
    - other MAOIs, buspirone or dibenzazepine derivative drugs (e.g. tricyclic antidepressants, perphenazine or carbamazepine), selective serotonin re-uptake inhibitors (SSRIs) or serotonin noradrenaline re-uptake inhibitors (SNRIs, e.g. venlafaxine). Phenelzine should not be taken for 14 days either before or after these medicines.
    - clomipramine or imipramine - 21 days should elapse before starting Phenelzine.

If you are not sure which medicines you are already taking, please ask your doctor or pharmacist.

Phenelzine with food, drink and alcohol
Phenelzine reacts with a substance called tyramine which is found in some foods and drinks (see lists below).
If you eat or drink anything containing tyramine while you are taking Phenelzine, or within 14 days of taking Phenelzine, you may have a very severe rise in blood pressure.
This will happen soon after eating the food and you may get a violent headache, pounding

heart, stiff neck, flushing, sweating or you may be sick. The severity of the reaction depends on the amount of tyramine you eat and may be mild or could be dangerous, even fatal.
If you feel such a reaction happening, tell your doctor or go to your nearest hospital accident and emergency department immediately.

Do not eat:
Cheese (cooked or plain), liver, yoghurt, yeast/meat extracts (e.g. ***Marmite, Oxo, Bovril*** or Brewer's yeast), flavoured textured vegetable protein, broad bean pods, protein which has been allowed to age, degrade or ferment (e.g. hung game, pickled herrings or dry sausage such as salami or pepperoni), fermented soya bean extract, excessive amounts of chocolate.

Do not drink:
Alcohol, non-alcoholic beer, lager or wine. You may drink a reasonable amount of tea or coffee but not to excess.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Phenelzine is not recommended for use during pregnancy, especially during the first and last trimesters.

Do not breast-feed if you are taking Phenelzine.

As with any medicine, ask your doctor or pharmacist for advice.

Driving and using machines
Phenelzine might cause drowsiness or blurred vision. Do not drive or operate machinery until you know if the tablets affect you in this way.

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

3. How to take Phenelzine

Always take Phenelzine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how many tablets to take and for how long you should take them.
Swallow the tablets with some water. You can take them with or without food.

Your blood pressure should be checked frequently by your doctor and Phenelzine should be stopped if palpitations or frequent headaches occur.

Use in adults
The usual starting dose is one tablet three times a day. Your doctor will decide what dose is best for you. Follow the instructions on the label and do not change the dose unless your doctor tells you to.

Use in the elderly (over 65 years)
The dosage is the same as for adults, but elderly patients may have an increased risk of side effects and are more likely to be taking other medicines which Phenelzine may react with (see section 2 "Other medicines and Phenelzine").

Use in children

Phenelzine is not recommended for use in children under 16 years old.

Important – It may take four weeks before you feel the full effect of the tablets.

If these tablets are not helping you after you have taken them for about two weeks, your doctor may increase the dose to a maximum of one tablet four times a day.
In hospitals, doses of up to two tablets three times a day may be used.
Once the tablets are helping your depression, your doctor may slowly lower the dose. This may be as low as one tablet every other day.

If you take more Phenelzine than you should
If you accidentally take more tablets than you were told to, or you suspect that a child has swallowed the tablets, contact your doctor straight away or go to your nearest hospital accident and emergency department immediately. Take this leaflet and the pack of tablets along with you, if you can.

If you forget to take Phenelzine
If you forget to take your tablets, take your next dose at the usual time and continue taking the tablets according to your doctor's instructions. Do not take a double dose to make up for a forgotten individual dose.
If in doubt about what you should do, please contact your doctor or pharmacist.

If you stop taking Phenelzine
Do not stop taking Phenelzine suddenly unless your doctor tells you to. This may make you feel sick or unwell.
A few people may experience a more serious effect if Phenelzine is stopped suddenly. This may happen one to three days after stopping Phenelzine and symptoms may include:
- vomiting, nausea and feeling generally unwell
- nightmares, agitation, psychosis (seeing or hearing things that are not there, or believing things which are not true) and fits.

If this happens, tell your doctor immediately. Your doctor may give you a lower dose until your symptoms improve.

It is important to continue to follow all of the instructions contained within this leaflet for 14 days after you stop taking Phenelzine.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Phenelzine can cause side effects, although not everybody gets them.
Side effects are usually mild or moderate in severity and tend to disappear as treatment continues.

The **most serious** side effects are high blood pressure, which usually happens when the wrong food is eaten (see section 2 "Phenelzine with food, drink and alcohol"), and **neuroleptic malignant syndrome** (a serious, sometime life-threatening, condition which results in fever, faster breathing and pulse rate, sweating, muscle stiffness, changes in blood pressure and reduced consciousness). **If you feel this is happening to you, STOP TAKING the tablets and tell your doctor or go to your nearest hospital accident and emergency department immediately.**

Common side effects are:
- drowsiness, dizziness, weakness, tiredness and blurred vision (see section 2 "Driving and using machines")
- low blood pressure when standing or sitting up. You may feel giddy and about to faint. This effect is more common in the elderly
- water retention (can cause swollen ankles)

- nausea, vomiting, dry mouth, constipation
- insomnia (difficulty in sleeping)
- twitching, increased reflexes
- difficulty in achieving an orgasm
- changes in the blood related to liver problems (this may be identified in a blood test)

Uncommon side effects are:
- headache, nervousness, excitement, jitteriness, shaking, confusion, seeing or hearing things which are not there, fits
- changes in normal behaviour, speech changes (repeating the last word of a sentence), unusual eye movements
- loss of feeling in hands and feet
- rash, itching, sweating, nerve pain, bruising
- a feeling of pins and needles
- changes in the rhythm of the heart
- increased appetite and weight
- difficulty in passing urine
- impotence, delayed ejaculation
- high levels of sodium (salt) in the blood, symptoms may be tiredness, weakness, irritability and swelling
- abnormalities of blood cells, symptoms can include bleeding problems, weakness or pale skin colour, or frequent infections
- high pressure in the eye (glaucoma)
- lupus-like illness (a disease affecting the immune system)
- high levels of liver enzymes (this may be identified in a blood test)

Very rarely, other serious effects have been seen, these are:
- loss of co-ordination
- coma (being unconscious) delirium (disorientation, seeing or hearing things which are not there, delusions, and incoherent speech)
- neuroleptic malignant syndrome (a serious, sometimes life-threatening, condition which results in fever, faster breathing and pulse rate, sweating, muscle stiffness, changes in blood pressure and reduced consciousness)
- mania (excessive feeling of well being), rapidly developing anxiety
- schizophrenia, in people already at risk of developing it
- heart and lung problems following electroshock therapy (ECT)
- jaundice (yellowing of the skin), liver damage which may be serious or even fatal
- increased metabolism
- swollen glottis (top of the wind-pipe).

Too little sodium (salt) in the blood has been seen with all types of antidepressants. This may cause drowsiness, confusion or fits. It is more usually seen in the elderly.

If any of these side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Phenelzine

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

Blister pack: Do not store above 30°C.
HDPE bottle: This medicinal product does not require any special storage conditions.
Use within 60 days after first opening the bottle.

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

Do not throw away any 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 Phenelzine contains

Each film-coated tablet contains 15 mg phenelzine (as phenelzine sulfate).

The other ingredients are:
Core: mannitol (E421), Croscarmellose Sodium (E468), Povidone, Disodium Edetate, Sodium stearyl fumarate.
Coating: Polyvinyl Alcohol (E1203), Talc (E553b), Quinoline Yellow Aluminum Lake (E104), Titanium Dioxide (E171), Glyceryl monocaprylocaprate (Type I), Sodium Lauryl Sulfate, Iron Oxide Red (E172).

What Phenelzine looks like and contents of the pack

Pale orange coloured, round shaped, biconvex, film coated tablets debossed with 'P15' on one side and plain on the other side with approximate diameter 8.8 mm.

The tablets are supplied in the following packs:

White, opaque, high-density polyethylene (HDPE) bottle fitted with a child-resistant white, polypropylene (PP) cap with induction heat sealed liner containing silica gel and activated carbon canister, with 60 film-coated tablets.

Alu-Alu blisters in a carton containing 30 and 100 film-coated tablets.

Marketing Authorisation Holder and Manufacturer

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PL 06464/3137 Phenelzine 15 mg film-coated tablets

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