PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

DEGRANOL (200 mg tablet)

Read all of this leaflet carefully before you start taking DEGRANOL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- DEGRANOL has been prescribed for you personally and you should not share DEGRANOL with other people. It may harm them, even if their symptoms are the same as yours.

WHAT DEGRANOL CONTAINS

Each tablet contains 200 mg carbamazepine.

The other ingredients are magnesium stearate, maize starch, microcrystalline cellulose 101, polysorbate 80, purified talc and sodium starch glycollate.

DEGRANOL is sugar-free.

WHAT DEGRANOL IS USED FOR

DEGRANOL is an anticonvulsant medicine used to prevent fits. DEGRANOL is also used in the treatment of certain types of pain and to control mood disorders.

BEFORE YOU TAKE DEGRANOL

Do not take DEGRANOL:

- If you are **allergic** (hypersensitive) to carbamazepine or similar medicines such as oxcarbazepine, tricyclic antidepressants (amitriptyline or imipramine), or any other ingredients of DEGRANOL (see **WHAT DEGRANOL CONTAINS**).
- If you have any heart problems.
- If you have ever had problems with your bone marrow.
- If you have a blood disorder called porphyria.
- If you have taken medicines called monoamine oxidase inhibitors (MAOIs), used to treat depression, within the last 14 days.
- If you are pregnant and breastfeeding.
- If you have liver disease.

Take special care with DEGRANOL

- If you have an inherited allelic variant HLA-B*1502 as you are genetically at greater risk of having serious skin reactions. This allele occurs almost exclusively in patients with ancestry across broad areas of Asia, including South Asian Indians.
- If you have tumours of the liver.
- If you have suicidal tendencies.
- If you have mixed seizures.
- If you have heart, liver or kidney disorders.
- If you have glaucoma (raised pressure in the eye).
- Blood counts and liver function tests should be done before starting treatment with DEGRANOL.
- Tolerance to DEGRANOL may develop and it can be overcome by increasing and adjusting the maintenance dose.
- Do not stop taking DEGRANOL suddenly. DEGRANOL should be withdrawn gradually to minimise the risk of a potential seizure. The change-over period to another antiepileptic medicine should be done in combination with diazepam or a barbiturate.

- Do not take alcohol during treatment with DEGRANOL.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding while taking DEGRANOL, please consult your doctor, pharmacist or other healthcare provider for advice.

Driving and using machinery

Reaction time may be increased by DEGRANOL. The patient's safety as a road user or operator of machines may be impaired as a consequence. Do not operate machines or drive whilst taking DEGRANOL, until you know how you will react to it.

Taking other medicines with DEGRANOL

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of DEGRANOL with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

The following medicines may cause an interaction when used in combination with DEGRANOL:

- Hormone contraceptives, e.g. pills, patches, injections or implants. DEGRANOL affects the way the contraceptive works in your body, and you may get breakthrough bleeding or spotting. It may also make the contraceptive less effective and there will be a risk of getting pregnant. Your doctor will be able to advise you about this, and you should think about using other contraceptives.
- Hormone Replacement Therapy (HRT). DEGRANOL can make HRT less effective.
- Any medicines for depression or anxiety.
- Corticosteroids ('steroids'). You might be taking these for inflammatory conditions such as asthma, inflammatory bowel disease, muscle and joint pains.
- Anticoagulants to stop your blood clotting (e.g. warfarin).
- Antibiotics to treat infections, including skin infections and TB (tuberculosis).

- Antifungals to treat fungal infections.
- Painkillers containing paracetamol, tramadol, methadone or buprenorphine.
- Other medicines to treat epilepsy (e.g. oxcarbazepine, phenobarbitone, phenytoin, primidone, clonazepam or valproic acid).
- Medicines for high blood pressure or heart problems.
- Antihistamines (medicines to treat allergy such as hay fever, itch, etc.).
- Diuretics (water tablets).
- Cimetidine or omeprazole (medicines to treat stomach ulcers).
- Isotretinoin (a medicine for the treatment of acne).
- Metoclopramide (an anti-nausea medication).
- Acetazolamide (a medicine to treat glaucoma (increased pressure in the eye)).
- Danazol (medicine used for the treatment of endometriosis).
- Theophylline or aminophylline (used in the treatment of asthma).
- Ciclosporin (an immunosuppressant, used after transplant operations, but also sometimes in the treatment of arthritis or psoriasis).
- Medicines used to treat schizophrenia.
- Medicines used to treat cancer.
- Medicines used to relax muscle (used in anaesthesia).
- Bupropion (used to help stop smoking).
- A herbal remedy called St John's Wort or Hypericum perforatum (used to treat depression).
- Vitamin supplements containing vitamin B (nicotinamide).

HOW TO TAKE DEGRANOL

Always use DEGRANOL exactly as your doctor has told you. You must check with your doctor if you are not sure.

The dose of DEGRANOL for **trigeminal neuralgia** (a nerve disorder that causes a stabbing pain in parts of your face).

An initial dose of 200 mg twice daily gradually increasing until a suitable response is obtained.

The usual dosage required is one tablet three or four times daily.

In elderly or hypersensitive patients an initial dose of half a tablet (100 mg) twice daily is recommended.

Epilepsy

*Dosage for adults***:**

Initially 100 mg to 200 mg once or twice daily, followed by a slow increase until usually, at a level of 400 mg twice or three times daily, the best response is obtained. In some instances 1 600 mg in 3 to 4 divided doses may be necessary.

Dosage for children:

Administered in several fractional doses, usually 10 to 20 mg/kg per day.

5 to 10 years: 400 to 600 mg (2 to 3 tablets) per day.

10 to 15 years: 600 to 1 000 mg (3 to 5 tablets) per day.

Even if you feel better, do not stop taking DEGRANOL without talking to your doctor.

If you take more DEGRANOL than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison centre.

If you forget to take DEGRANOL

If you miss a dose of DEGRANOL, take it as soon as you remember. If it is nearly time for the next dose, skip the missed dose and go back to your normal dosing schedule. Do not take a double dose to make up for forgotten individual doses.

Do not stop taking DEGRANOL without talking to your doctor first

Do not stop taking DEGRANOL unless your doctor tells you to. If you suddenly stop taking DEGRANOL you may have a seizure.

Even when you feel better, do not stop taking DEGRANOL. Talk to your doctor first. If you have any further questions on the use of DEGRANOL, ask your doctor.

POSSIBLE SIDE EFFECTS

DEGRANOL can cause side effects, although not everybody gets them.

Tell your doctor if you experience any of the following symptoms after taking DEGRANOL.

If any of the following happens, stop taking DEGRANOL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- Rash or itching,
- Fainting,
- Yellowing of your skin and eyes (also called jaundice).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to DEGRANOL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Fever, sore throat, rash, sores in your mouth, swollen glands or more easily getting infections (signs of lack of white blood cells).
- Tiredness, headache, being short of breath when exercising, dizziness, looking pale, frequent infections leading to fever, chills, sore throat (lack of all blood cells).
- Serious skin reactions such as rash, red skin, blistering of the lips, eyes or mouth, or skin peeling accompanied by fever.

- Mouth ulcers or unexplained bruising or bleeding.
- Sore throat and/or high temperature.
- Swollen ankles, feet or lower legs.
- Any signs of nervousness or confusion.
- Fever, skin rash, joint pain and abnormalities in blood and liver function tests (these may be the signs of a multi-organ sensitivity disorder).
- Pain in the area near the stomach, vomiting, loss of appetite (signs of pancreatitis).
- Darkening of urine (signs of porphyria).
- Severe decreased urine output due to kidney disorders, blood in your urine.
- Lethargy, confusion, muscular twitching or significant worsening of convulsions (symptoms that may be linked to low sodium levels in your blood).
- Fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light (signs of meningitis).
- Muscular stiffness, high fever, altered consciousness, high blood pressure, excessive salivation (signs of neuroleptic malignant syndrome).
- Irregular heartbeat, chest pain.
- Disturbed consciousness, fainting.

These symptoms can be serious. You may need urgent medical attention.

Tell your doctor as soon as possible if you notice any of the following:

- Loss of muscle coordination.
- Swelling of your ankles, feet or lower legs (oedema).
- Changes in behaviour, confusion, weakness.
- Blurred vision, double vision, itching with redness and swelling in your eye (conjunctivitis), feeling increased pressure or pain in your eye (glaucoma).
- Trembling, uncontrolled body movements, muscle spasms, uncontrolled eye movements.
- Difficulty in speaking and slurred speech.

- Nausea, vomiting, dry mouth.
- Depression with restlessness, nervousness, mental or mood changes, seeing or hearing things that do not exist (hallucinations).
- Ringing sound in your ears, decreased hearing.
- Numbness, tingling in hands and feet.
- Frequent urination, decrease in amount of urine, taste disturbances.

Not all side effects reported for DEGRANOL are included in this leaflet. Should your general health worsen while taking DEGRANOL or if you notice any side effects not listed in this leaflet, please consult your doctor, pharmacist or other healthcare professional for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF DEGRANOL

Store at or below 25 °C. Protect from moisture.

Store in airtight containers.

Do not store in a bathroom.

Do not use DEGRANOL after the expiry date which is stated on the box after the letters EXP. The expiry date refers to the last day of that month.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

PRESENTATION OF DEGRANOL

100 or 500 tablets are packed in a white polypropylene container and sealed with a white low density polyethylene cap together with a white foam or rayon insert.

56 or 84 tablets are packed in metallised lay flat bags which is composed of metallised

polyester/laminant/ opaque white linear low density polyethylene.

56 or 84 tablets are packed in Ziplock layflat linear low density polyethylene bags with a key profile zipper and ribbed flanges.

Tablets are packed in clear polyvinylchloride blister strips sealed with an aluminium foil backing. The blister strips are packed into an outer cardboard carton together with a leaflet.

Not all packs and pack sizes are necessarily marketed.

IDENTIFICATION OF DEGRANOL

A white round, flat tablet, with bevelled edges, plain on the one side and bisected on the other.

REGISTRATION NUMBER

G/2.5/220

NAME AND ADDRESS OF REGISTRATION HOLDER

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead, 2191

Hotline: 0800 122 912

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