

DEPRILEPT TABLETS

Escitalopram Oxalate (10mg, 20mg)

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What **DEPRILEPT** is used for

DEPRILEPT is used to treat:

- depression (major depressive episodes)
- anxiety disorders (such as panic disorder, social anxiety disorder)

How **DEPRILEPT** works

DEPRILEPT contains escitalopram which belongs to a group of medicines called SSRIs (selective serotonin reuptake inhibitors) which are antidepressants.

They are thought to work by their actions on serotonin-system in the brain by increasing the serotonin level. Disturbance in the serotonin levels are thought to be responsible for depression and related diseases.

Ask your doctor if you have any questions about why **DEPRILEPT** have been prescribed for you.

Before you use **DEPRILEPT**

- When you must not use it

Do not take **DEPRILEPT** if you are:

- Allergic (hypersensitive) to escitalopram, citalopram or any of the other ingredients of **DEPRILEPT** as mentioned in **Product Description**
- An allergic reaction may include:
 - rash,
 - itching
 - swelling of face, lips or hands/feet
 - breathing difficulties
- Taking medicines that belong to a group called monoamine oxidase inhibitors (MAOIs) e.g. moclobemide (used for treatment

of depression), linezolid (antibiotic) and selegiline (used to treat Parkinson's disease).

- Taking pimozide (antipsychotic medicine used to treat certain mental disorders).
- Born with or have had an episode of abnormal heart rhythm.
- Taking other medicines that are known to affect the heart's rhythm (such as phenothiazine medicines, pimozide, haloperidol, sparfloxacin, moxifloxacin, erythromycin, pentamidine, halofantrine, astemizole, mizolastine or certain medicines for irregular heartbeat).

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

DEPRILEPT should not be used in the treatment of children and adolescents under 18 years of the age.

- Before you start to use it

If you take **DEPRILEPT** near the end of your pregnancy there may be an increased risk of heavy vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your doctor should be aware that you are taking **DEPRILEPT** so they can advise you

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Take special care with **DEPRILEPT, tell your doctor or pharmacist if:**

- You have or have had epilepsy (seizure or fits) or an increase in the seizure frequency
- You have a history of mania
- You have risk of having low sodium level (e.g. liver scarring) or taking medicines known to cause low sodium level
- You are diabetic (dose of insulin and/or oral anti-diabetic medicines may need to be adjusted)
- You are receiving electroconvulsive therapy
- You have a history of bleeding or bruising more easily than normal

- You suffer from any heart disease (decreased heart rate, abnormal heart rhythm, heart failure or recent heart attack)
- You have problem with your kidney(s) or liver

If you have not told your doctor about any of the above, tell them before you start taking **DEPRILEPT**.

Your doctor may order ECG test before starting treatment and also while on treatment to monitor your condition.

Pregnancy and Lactation

Inform your doctor if you are pregnant, you think you might be pregnant or you are planning to get pregnant. Do not take **DEPRILEPT** if you are pregnant unless you and your doctor have discussed the risks and benefits involved.

When taken during pregnancy, particularly in the last three months of pregnancy, medicines like escitalopram may affect the general condition of your newborn baby and may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN) making the baby breathe faster and appear bluish. It may also cause:

- difficulty in breathing
- feeding difficulty
- vomiting
- low blood glucose level
- changes of muscle tone
- over-responsive reflexes
- shaking
- irritability
- feeling of tiredness, drowsiness, or lack of energy
- constant crying and difficulty sleeping.

These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your doctor immediately.

Escitalopram is known to be found in breast milk. Tell your doctor if you are currently breast-feeding.

Your doctor would decide about your treatment with **DEPRILEPT**.

This medicine contains lactose monohydrate. If you have been told by your doctor that you have intolerance to

some sugars, contact your doctor before taking this medicinal product.

- Taking other medicines

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

Some medicines may be affected by **DEPRILEPT** or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor or pharmacist will advise you accordingly.

In particular, tell your doctor or pharmacist if you are taking:

- Anti-malarial medicine such as mefloquin
- Risperidone, thioridazine, (medicines called antipsychotics used to treat certain mental and emotional conditions)
- Sumatriptan and similar medicines (used to treat migraine) and tramadol (used against severe pain)
- Fluvoxamine, bupropion, desipramine, clomipramine, nortriptyline, lithium, thioxanthenes (used for certain type of mental illness or disorders)
- Cimetidine, esomeprazole, lansoprazole and omeprazole (used to treat stomach ulcers) and ticlopidine (used to reduce the risk of stroke)
- St. John's Wort- a herbal remedy used for depression
- Acetylsalicylic acid (aspirin, used to thin the blood and relieve pain)
- Non-steroidal anti-inflammatory drugs (medicines used for pain relief)
- Warfarin and dipyridamole, (medicines used to thin the blood)
- Flecainide, propafenone, and metoprolol (used in heart diseases)
- Ketoconazole (used to treat fungal infections)
- Carbamazepine (used to treat epilepsy)
- Theophylline (used to treat respiratory disorders)

Please also see the list of medicines mentioned in the section. **Before you use DEPRILEPT.**

Escitalopram may be started 14 days after discontinuing treatment with nonselective irreversible MAOI (e.g. phenelzine). At least 7 days should

elapse after discontinuing escitalopram treatment, before starting a non-selective, irreversible MAOI.

Your doctor will know when it is safe to start **DEPRILEPT** after the MAOI has been stopped.

How to use DEPRILEPT

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

- How much to use

Always take **DEPRILEPT** exactly as your doctor has told you. Ask your doctor or pharmacist if you are unsure of the correct dose for you. They will tell you exactly how much to take it.

Adults over the age of 18 years:

Your doctor will decide what dose you will receive.

The standard dose for this medicine is 10 mg per day. Your doctor may modify your dose depending on your condition (which may range from 5 mg-20 mg).

Do not change the dose of your medicine without talking to your doctor first.

- When to use it

Take **DEPRILEPT** once a day at the same time each day. Taking it at same time each day will have the best effect. It will also help you remember when to take it.

Take it with or without food daily. The tablet needs to be swallowed as a whole with a glass of water.

- How long to use it

Continue to take **DEPRILEPT** for as long as your doctor recommends.

Do not stop using **DEPRILEPT** until your doctor tells you to, even if you feel better. If **DEPRILEPT** is stopped suddenly you may experience symptoms such as:

- dizziness,
- pins and needles, electric shock sensations,
- sleep disturbances,
- feeling anxious or agitated,
- headaches,
- feeling sick, vomiting,
- sweating,
- tremor,

- feeling confused,
- feeling emotional or irritable,
- diarrhoea,
- visual disturbances,
- Pounding of or irregular heartbeats.

Generally these events are mild to moderate and are self-limiting; however in some people they may be severe and/or prolonged. Treatment would normally last for several months after you feel well again.

Individuals vary greatly in their response to escitalopram. Your doctor will check your progress at regular intervals.

When you have completed your course of treatment, the dose of **DEPRILEPT** is gradually reduced over a couple of weeks rather than stopped abruptly. Your doctor will tell you how to reduce the dosage so that you do not get these unwanted effects.

- If you forget to use it

If you miss a dose and remember in less than 12 hours, take it straight away, and then go back to taking it as you would normally. Otherwise, if it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to. Do not take a double dose to make up for the dose you have missed.

- If you use too much (overdose)

Immediately telephone your doctor for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too many **DEPRILEPT**. The symptoms of overdose are:

- feeling of being lightheaded,
- shaking,
- fits,
- prolonged unconsciousness,
- nausea/vomiting,
- low blood pressure,
- increased/irregular heart beat and
- low blood potassium and sodium level

You may need urgent medical attention. Do this even if there are no signs of discomfort or poisoning. Show them the pack of tablets

While you are using DEPRILEPT

- Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking **DEPRILEPT**.

You may have thoughts of self-harm or killing yourself during treatment of depression. This risk of suicide generally increases during early stages of treatment. It is possible that these symptoms continue or get worse until the full antidepressant effect of the medicine becomes apparent. This is more likely to occur if you are young adult i.e 18 to 24 years of age and you have not used antidepressant medicines before.

Tell your doctor immediately if you experience anything like that.

Ask your doctor or pharmacist for advice before taking any medicine.

- Things you must not do

It is not advisable to drink alcohol while you are on **DEPRILEPT** treatment.

Do not take **DEPRILEPT** 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 as you.

If you are using other medicines along with **DEPRILEPT** do not stop taking any of the medicine on your own. Talk to your doctor or pharmacist if you need any help.

- Things to be careful of

Though escitalopram has been shown not to affect intellectual function or psychomotor performance, medicines used to treat mental disorders may impair judgment or skills, if this occurs do not drive or operate machinery.

Make sure you know how you react to **DEPRILEPT** before you drive a car, operate machinery, or do anything else that could be dangerous.

Pay attention for any of the following warning signs of suicide-related behavior while taking **DEPRILEPT**.

Suicide related behaviours (suicide attempt and suicidal thoughts), and hostility (predominately aggression, oppositional behaviour and anger) were more frequently reported among children and adolescents taking

antidepressants. In addition, long-term safety in children and adolescents concerning growth, maturation and cognitive and behavioural development are lacking

Side effects

Like all medicines **DEPRILEPT** can cause side effects, although not everybody gets them.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Side effects are most prominent during the first one or two weeks of treatment and usually decrease in intensity and frequency with continued treatment.

Very Serious Side Effects

If any of the following happen, tell your doctor immediately or go to the casualty department at your nearest hospital.

- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.
- Red, often itchy spots, similar to the rash of measles with blistering of the skin, mouth, eyes and genitals.
- Thoughts about suicide and self-harm, suicidal behavior or tendency, actual suicide. Suicide has been reported with escitalopram use.
- High fever, agitation, confusion, trembling and abrupt contractions of muscles (these symptoms may be signs of a rare condition called serotonin syndrome).
- Serious heart problems including changes in heart beat or rhythm; shortness of breath, swelling of the feet or legs due to fluid build-up (heart failure, stroke, heart attack)
- Sudden and temporary loss of consciousness.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Serious Side Effects

Tell your doctor immediately if you notice any of the following:

- Bleeding or bruising more easily than normal.
- Uncontrollable twitching or jerking movements of the arms, legs or

eyes, movement disorder, seizure/fits, rigid posture, slow movements and a shuffling, unbalanced walk.

- Loss of memory, difficulty in speaking, uncontrollable muscle spasms affecting the eyes, head, neck and body.
- Dizziness when you stand up due to low blood pressure.
- Liver problems including liver inflammation and liver failure.
- False or disoriented sensory experience that appears to be real perception (hallucinations), loss of normal sense of personal identity and reality (depersonalization), aggression, anger, feeling elated, or emotionally "high" (mania), worsening of depression, severe confusion, a fixed, irrational idea not shared by others, disorientation, feeling unreal, mood swings, mental illness causing severe suspiciousness, impaired concentration.
- Persistent painful erection of the penis which occurs without sexual arousal.
- Muscle pain or weakness of muscles.
- Severe upper stomach pain, often with nausea and vomiting.
- Little or no urine, drowsiness, nausea, vomiting, breathlessness, fatigue, weakness (acute kidney failure).
- Spontaneous abortion.
- Gastrointestinal bleeding including rectal bleeding.

The above list includes serious side effects that may require medical attention.

Others

Tell your doctor if you notice any of the following:

- Problem with your eye sight, pain and increased pressure behind eyes, double vision, dilated pupils.
- Changes in weight or changes in appetite, loose stool, constipation, dry mouth, indigestion, tooth ache, cramps, heartburn.
- Decreased feeling or sensitivity, especially in the skin, sensation of pricking, tingling, or creeping on the skin.
- Throbbing headache, sleep disorder. Abnormal dreaming, restlessness, anxiety.

- Pain or discomfort on passing urine, abnormal urine frequency, urinary tract infections.
- Pain in the joints and muscle, jaw stiffness.
- Hot flushes.
- Increased sensitivity to sunlight.
- Failure of ejaculation in males, inability to get or maintain an erection, decreased sex drive, lack of orgasm in females.
- Heavy or irregular menstrual bleeding, unusual secretion of breast milk, menstrual cramps and menstrual disorder.
- diabetes

Laboratory Abnormalities

- Abnormal liver function tests, increased bilirubin.
- Low sodium levels in the blood.
- Abnormal blood sugar levels.
- Abnormal ECG.
- Blood clotting abnormal.
- Increased blood cholesterol.
- High prolactin levels in the blood.
- Low hemoglobin and blood cell counts.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and disposal of DEPRILEPT

- Storage

Store below 30°C, protected from moisture.

Keep out of the reach of children.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What DEPRILEPT looks like

DEPRILEPT TABLETS 10 mg

White to off white oval biconvex film coated tablets debossed with 'E' and '8'

on either side of the eye breakline on one side and plain on the other side.

DEPRILEPT TABLETS 20 mg

White to off white oval biconvex film coated tablets debossed with 'E' and '9' on either side of the eye breakline on one side and plain on the other side.

- Ingredients

- Active ingredient

Escitalopram 10mg or 20mg

- Inactive ingredients

Microcrystalline Cellulose (PH101, Lactose Monohydrate, Copovidone (Plasdone-S-630), Maize Starch (Purity 21), Purified water, Silicified MCC (Prosolv SMCC 90), Croscarmellose Sodium (AC-DI-SOL), Purified Talc, Colloidal anhydrous silica, Magnesium stearate, Opadry White OY-S-58910

- MAL number

DEPRILEPT TABLET 10 mg

MAL10100144AZ

DEPRILEPT TABLET 20 mg

MAL10100145AZ

Manufacturer:

SUN PHARMACEUTICAL INDUSTRIES LIMITED
Paonta Sahib, Dist Sirmour
Himachal Pradesh-173025
INDIA

Product registration holder:

RANBAXY (MALAYSIA) SDN. BHD.
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