1.4 Product Information

1.4.3 Patient information leaflet

(For All Products not subject to Medical Prescription)

HENKA 60 (Duloxetine Delayed Release Capsules USP 60mg)

PACKAGE LEAFLET: INFORMATION FOR THE USER

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

- 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 or your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your or your child's.
- If you or your child 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 Duloxetine Delayed Release Capsules USP 60mg is and what it is used for
2. What you need to know before you take Duloxetine Delayed Release Capsules USP 60mg
3. How to take Duloxetine Delayed Release Capsules USP 60mg
4. Possible side effects
5. How to store Duloxetine Delayed Release Capsules USP 60mg
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1. What Duloxetine Delayed Release Capsules USP 60mg is and what it is used for

What Duloxetine Delayed Release Capsules USP 60mg is

Duloxetine Delayed Release USP 60mg is a prescription medicine used to treat a certain type of depression called Major Depressive Disorder (MDD). Duloxetine Delayed Release USP 60mg belongs to a class of medicines known as SNRIs (or serotonin-norepinephrine reuptake inhibitors).

Duloxetine Delayed Release USP 60mg is also used to treat or manage:

- Generalized Anxiety Disorder (GAD)
- Diabetic Peripheral Neuropathic Pain (DPNP)
- Fibromyalgia (FM)
- Chronic Musculoskeletal Pain

2. What you need to know before you take Duloxetine Delayed Release Capsules USP 60mg

Before starting Duloxetine Delayed Release USP 60mg, tell your healthcare provider if you:

- have heart problems or high blood pressure
- have diabetes (Duloxetine Delayed Release USP 60mg treatment makes it harder for some people with diabetes to control their blood sugar)
- have liver problems
- have kidney problems
- have glaucoma
- have or had seizures or convulsions
- have bipolar disorder or mania
- have low sodium levels in your blood
- have delayed stomach emptying
- have or had bleeding problems
- are pregnant or plan to become pregnant. Duloxetine Delayed Release USP 60mg may harm your unborn baby. Talk to your healthcare provider about the risk to your unborn baby if you take Duloxetine Delayed Release USP 60mg during pregnancy.
    - Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with Duloxetine Delayed Release USP 60mg.
    - If you become pregnant while taking Duloxetine Delayed Release USP 60mg, talk to your healthcare provider about registering with the Duloxetine Delayed Release USP 60mg Pregnancy Registry. You can register by calling 1-866-814-6975 or by visiting www.Duloxetine Delayed Release USP 60mgpregnancyregistry.com. The purpose of this registry is to monitor the pregnancy outcomes in women who have been treated with Duloxetine Delayed Release USP 60mg at any time during pregnancy.

- are breastfeeding or plan to breastfeed. Duloxetine Delayed Release USP 60mg passes into your breast milk and may harm your baby. Talk to your healthcare provider about the best way to feed your baby while taking Duloxetine Delayed Release USP 60mg.

Tell your healthcare provider about all the medicines that you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Duloxetine Delayed Release USP 60mg and some medicines may interact with each other, may not work as well, or may cause serious side effects.

Especially tell your healthcare provider if you take:

- triptans used to treat migraine headache
- medicines used to treat mood, anxiety, psychotic or thought disorders, including tricyclics, lithium, buspirone, SSRIs, SNRIs or MAOIs
- tramadol and fentanyl
- amphetamines
- cimetidine
- the antibiotics ciprofloxacin, enoxacin
- medicine to treat irregular heart rate (like propafenone, flecainide, quinidine)
- theophylline
- the blood thinner warfarin (Coumadin, Jantoven)
- non-steroidal anti-inflammatory drug (NSAID) (like ibuprofen, naproxen or aspirin).
- over-the-counter supplements such as tryptophan or St. John's Wort
- thioridazine (Mellaril). Mellaril together with Duloxetine Delayed Release USP 60mg can cause serious heart rhythm problems or sudden death.
- Ask your healthcare provider for a list of these medicines if you are not sure.

- Do not take Duloxetine Delayed Release USP 60mg with any other medicine that contain duloxetine.

3. How to take Duloxetine Delayed Release Capsules USP 60mg

- Duloxetine Delayed Release USP 60mg can cause sleepiness or may affect your ability to make decisions, think clearly, or react quickly. You should not drive, operate heavy

machinery, or do other dangerous activities until you know how Duloxetine Delayed Release USP 60mg affects you.

- Use of Duloxetine Delayed Release USP 60mg concomitantly with heavy alcohol intake may be associated with severe liver injury. Avoid heavy alcohol use while taking Duloxetine Delayed Release USP 60mg.

4. Possible side effects

Common possible side effects in people who take Duloxetine Delayed Release USP 60mg include:

1. liver damage. Symptoms may include:

- itching
- right upper abdominal pain
- dark urine
- yellow skin or eyes
- enlarged liver
- increased liver enzymes

2. changes in blood pressure and falls. Monitor your blood pressure before starting and throughout treatment. Duloxetine Delayed Release USP 60mg may:

- increase your blood pressure.
- decrease your blood pressure when standing and cause dizziness or fainting, mostly when first starting Duloxetine Delayed Release USP 60mg or when increasing the dose.
- increase risk of falls, especially in elderly.

3. Serotonin Syndrome: This condition can be life-threatening and symptoms may include:

- agitation, hallucinations, coma or other changes in mental status
- coordination problems or muscle twitching (overactive reflexes)
- racing heartbeat, high or low blood pressure
- sweating or fever
- nausea, vomiting, or diarrhoea
- muscle rigidity
- dizziness

- flushing
- tremor
- seizures

4. abnormal bleeding: Duloxetine Delayed Release USP 60mg and other antidepressant medicines may increase your risk of bleeding or bruising, especially if you take the blood thinner warfarin (Coumadin, Jantoven), a non-steroidal anti-inflammatory drug (NSAIDs, like ibuprofen or naproxen), or aspirin.

5. severe skin reactions: Duloxetine Delayed Release USP 60mg may cause serious skin reactions that may require stopping its use. This may need to be treated in a hospital and may be life-threatening. Call your healthcare provider right away or get emergency help if you have skin blisters, peeling rash, sores in the mouth, hives or any other allergic reactions.

6. discontinuation symptoms: Do not stop Duloxetine Delayed Release USP 60mg without first talking to your healthcare provider. Stopping Duloxetine Delayed Release USP 60mg too quickly or changing from another antidepressant too quickly may result in serious symptoms including:

- anxiety
- irritability
- feeling tired or problems sleeping
- headache
- sweating
- dizziness
- electric shock-like sensations
- vomiting or nausea
- diarrhea

7. manic episodes:

- greatly increased energy
- severe trouble sleeping
- racing thoughts
- reckless behavior
- unusually grand ideas
- excessive happiness or irritability

- talking more or faster than usual

8. visual problems:

- eye pain
- changes in vision
- swelling or redness in or around the eye

Only some people are at risk for these problems. You may want to undergo an eye examination to see if you are at risk and receive preventative treatment if you are.

9. Seizures or convulsions

10. low salt (sodium) levels in the blood. Elderly people may be at greater risk for this. Symptoms may include:

- headache
- weakness or feeling unsteady
- confusion, problems concentrating or thinking or memory problems

11. problems with urination. Symptoms may include:

- decreased urine flow
- unable to pass any urine

The most common side effects of Duloxetine Delayed Release USP 60mg include:

- nausea
- dry mouth
- sleepiness
- fatigue
- constipation
- loss of appetite
- increased sweating
- dizziness

Common possible side effects in children and adolescents who take Duloxetine Delayed Release USP 60mg include:

- nausea
- decreased weight
- dizziness

Side effects in adults may also occur in children and adolescents who take Duloxetine Delayed Release USP 60mg. Children and adolescents should have height and weight monitored during treatment.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of Duloxetine Delayed Release USP 60mg. For more information, ask your healthcare provider or pharmacist.

5. How to store Duloxetine Delayed Release Capsules USP 60mg

• Store Duloxetine Delayed Release USP 60mg at room temperature between 68°F to 77°F (20°C to 25°C).

Keep Duloxetine Delayed Release USP 60mg and all medicines out of the reach of children.

General information about the safe and effective use of Duloxetine Delayed Release USP 60mg.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Duloxetine Delayed Release USP 60mg for a condition for which it was not prescribed. Do not give Duloxetine Delayed Release USP 60mg to other people, even if they have the same symptoms that you have. It may harm them.

6. Contents of the pack and other information

What Duloxetine Delayed Release Capsules USP 60mg contains

Active ingredient: Duloxetine hydrochloride

Inactive ingredients: Sugar spheres, (Pharmaspheres 710-850µ) (#20/25), Hypromellose 2910, 5cps, (Methocel E5 LV Premium), Crospovidone, (Kollidon CL M), Talc, (Luzenac Pharma), Sucrose, P.G Sugar # 40 # 80, HPMC AS 716 F, (ENTERACT), Triethyl citrate, Iso Propyl alcohol.

FD&C Blue No. 2, gelatin, hypromellose, hydroxypropyl methylcellulose acetate succinate, sodium lauryl sulfate, sucrose, sugar spheres, talc, titanium dioxide, and triethyl citrate. The 20 and 60 mg capsules also contain iron oxide yellow.

What Montelukast chewable tablets 5 mg looks like and contents of the pack

Duloxetine Delayed-Release Capsules USP 60mg is opaque blue cap/ Opaque green body size '1' hard gelatin capsule imprinted with 'H' on cap and '192' on body, filled with white to off white colored pellets.

Lidding Foil: 25µ Plain Aluminium foil (Hard tempered) with 3-6 GSM HSL coating on bright side, Width 152mm.

Base Foil: 156±1mm/0.25mm ± 10% Glass clear PVC/PVdC 40gsm ± 10%.

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Marketing Authorization Holder and Manufacturer

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