Take special care with TARDISC XL 60 because it contains important information for you. This medicine is available without prescription. However, you still need to use TARDISC XL 60 Prolonged Release Tablets carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you 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 TARDISC XL 60 is and what it is used for
2. What you need to know before you take TARDISC XL 60
3. How to take TARDISC XL 60
4. Possible side effects
5. How to store TARDISC XL 60
6. Contact of the pack and other information

1. WHAT TARDISC XL 60 IS AND WHAT IT IS USED FOR

The name of your medicine is TARDISC XL 60 Prolonged Release Tablets (referred to as TARDISC XL 60) throughout this leaflet. TARDISC XL 60 contains the active ingredient Isosorbide Mononitrate, which belongs to a group of medicines called nitrates. It is used to prevent an attack of angina pectoris (chest pain) from happening. Angina is a crushing pain or tightness in the chest, although the pain may also be felt in the neck or arm. The pain happens when the muscle in the heart does not receive enough oxygen for the work it has to do. TARDISC XL 60 works by improving the supply of blood and oxygen to the heart muscle. The tablets will release your medicine slowly and will treat your condition throughout the day.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TARDISC XL 60

DO NOT use these tablets to treat sudden chest pain (acute angina). Instead seek immediate medical attention. These tablets work too slowly to treat this and are only used to prevent an attack of angina from happening.

Do not take TARDISC XL 60 if:
- you are allergic (hypersensitive) to isosorbide mononitrate or any of the other ingredients of TARDISC XL 60 (listed in Section 6: Further information).
- you have ever had a stroke.
- you have severe anaemia.
- you have ever had a heart attack. It is important to reduce the risk of your body becoming less sensitive to the effects of TARDISC XL 60.

TARDISC XL 60 tablets should be swallowed with half a glass of water and must not be crushed or chewed.

The recommended dose is:
Adults: one TARDISC XL 60 tablet once daily in the morning. Your doctor may advise a different dose according to your symptoms, age and other medications. Your dose may be from half a tablet (30 mg) up to 2 tablets (120 mg) a day, both to be taken in the morning.

Use in Children
This medicine is not recommended for children.

Other medicines and TARDISC XL 60
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription and herbal medicines. This is because TARDISC XL 60 can affect the way some medicines work and some medicines can have an effect on TARDISC XL 60. You should not take Viagra (sildenafil) or other medicines from this group such as Cialis (tadalafil) or Levitra (vardenafil), drugs used for erectile dysfunction (impotence in men), whilst on TARDISC XL 60. If you take one of these drugs for erectile dysfunction, take a glyceryl trinitrate tablet (follow the instructions given on the label). Very occasionally, some people see the remains of the tablet in their bowel motions. This is quite normal and does not mean that the medicine has not been released.

If you take more TARDISC XL 60 than you should
If you take too many tablets, or someone else has taken any of them by accident, contact your nearest hospital casualty department or tell your doctor immediately. Remember to take the following to show the doctor:
- the leaflet and container.
- any remaining TARDISC XL 60 tablets
- any other medicines which you or the other person are taking.

Symptoms of an overdose can include:
- pounding headache, excitation, cold sweat, nausea (feeling sick), vomiting (being sick), vertigo (a feeling of dizziness or *spinning*), fainting, racing pulse.

If you forget to take TARDISC XL 60
If you forget to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, do not take the missed dose, just take the next dose on time.

Do not take a double dose to make up for a forgotten dose.
If you take TARDISC XL 60
Do not suddenly stop taking TARDISC XL 60 tablets, as this could make your angina worse. If your treatment is to be stopped this should be done gradually. Be sure to follow your doctor's instructions. Ask your doctor or pharmacist any further questions you may have.

4. POSSIBLE SIDE EFFECTS

Like all medicines, TARDISC XL 60 can cause side effects, although not everybody gets them.

Serious side effects:
If you suffer from any of the following signs, tell your doctor immediately:
- Fainting may occur but is uncommon.
- Rash and itching may occur but is rare.

Other side effects:
A number of side effects are known for isosorbide mononitrate, particularly when treatment begins.

Common (may affect up to 1 in 10 people):
- Headache is the most common side effect, but it usually disappears in time on continued use.
- Dizziness – this usually disappears with time.
- Lowering of blood pressure (which may make you feel dizzy or sick) especially when getting up from a lying or sitting position, but this usually disappear in time on continued use.
- Nausea (feeling sick)
- Tachycardia (fast heart beat)

Uncommon (may affect up to 1 in 100 people):
- Vomiting (being sick)
- Dizziness (elevate from a lying or sitting position, but this usually disappear in time on continued use.

Very rare (may affect up to 1 in 10,000 people):
- Muscle pain

If you develop any of these side effects and they are severe, or they get worse, or last for more than a few days, contact your doctor or pharmacist. If you have any other unexpected effects whilst taking this medicine, tell your doctor or pharmacist immediately.

5. HOW TO STORE TARDISC XL 60

Keep this medicine out of the sight and reach of children. These tablets should not be stored above 25°C. Do not transfer them to another container. Do not use TARDISC XL 60 after the expiry date which is stated on the blister and carton pack after “Exp”. The expiry date refers to the last day of that month. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required or past their expiry date. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What TARDISC XL 60 contains
- The active substance is isosorbide mononitrate (60 mg).
- The other ingredients are colloidal anhydrous silica, hypromellose 2208, lactose monohydrate (milk sugar), croscarmellose sodium (composed of sucrose and maltodextrin), magnesium stearate, iron oxide yellow E172.

What TARDISC XL 60 looks like and contents of the pack
TARDISC XL 60 tablets are light yellow, biconvex, oval-shaped, prolonged-release tablets, scored on both sides and marked “DX 31” on one side. TARDISC XL 60 is available in packs of 28 tablets in foil blister strips (2 blister packs of 14 tablets); 30 tablets in foil blister strips (3 blister packs of 10 tablets). Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:
Dexcel Pharma Ltd., 7 Spoweth Way, Drayton Fields, Daventry, Northamptonshire NN11 8PB, UK.

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