

# PATIENT INFORMATION LEAFLET Eltroxin 25, 50 and 100 microgram Tablets LEVOTHYROXINE SODIUM

Please read this leaflet carefully before you start to take your medicine. This leaflet does not contain all the information about your medicine. If you have any questions or you are not sure about anything ask your doctor or pharmacist.

#### THE NAME OF YOUR MEDICINE IS:

Eltroxin Tablets. Either 25, 50 or 100 micrograms.

#### THE ACTIVE INGREDIENT IS:

Each white tablet contains respectively
Anhydrous Levothyroxine Sodium
25 micrograms, 50 micrograms or
100 micrograms. Each tablet is scored
on one side and is engraved on the other
side with either 25mcg - FW41

50mcg - Eltroxin 50 100mcg - Eltroxin 100.

Eltroxin 25, 50 and 100 microgram Tablets are available in a blister pack of 28 Tablets.

#### WHAT ELSE IS IN YOUR MEDICINE:

As well as Levothyroxine Sodium, the tablets also contain Sodium Citrate, Lactose, Maize Starch, Acacia Powder, Magnesium Stearate and Purified Water.

The active ingredient is Levothyroxine Sodium. This is the new name for Thyroxine Sodium. The ingredient itself has not changed.

The active ingredient, Levothyroxine Sodium, although synthetic, is similar to the natural thyroid hormone (chemical messenger) in your body. Thyroid hormone is produced by the thyroid gland in your neck and regulates metabolism.

Eltroxin Tablets are made for the MA Holder, Goldshield Pharmaceuticals Ltd., NLA Tower, 12-16 Addiscombe Road, Croydon, Surrey, CR0 0XT, UK. by Custom Pharmaceuticals Ltd., Tecore House, Conway Street, Hove,

Eltroxin 25 microgram Tablets PL 12762/0016 Eltroxin 50 microgram Tablets PL 10972/0031 Eltroxin 100 microgram Tablets

PL 10972/0032

East Sussex, BN3 3LW, UK.

## WHAT IS YOUR MEDICINE USED FOR?

Eltroxin Tablets are given to you by your doctor because you have low levels of thyroid hormone (hypothyroidism - which may be from birth or due to any other reasons) and your metabolism is lower than normal. Thyroid hormone is vital for normal growth and development. Eltroxin Tablets make up for this lack of naturally occurring thyroid hormone. These tablets can be used for long term treatment.

## BEFORE YOU TAKE YOUR MEDICINE:

Do not take Levothyroxine tablets if:

- You ever have been allergic to Eltroxin Tablets or to any of the ingredients of Eltroxin Tablets.
- You ever have been allergic to other thyroid treatments.
- You have been told that your thyroid gland is overactive.

Tell your doctor if:

- · You are diabetic.
- · You have a heart condition.
- You have high levels of cholesterol in your blood.
- · You suffer from epilepsy.
- Female, you are pregnant or likely to become pregnant.
- You suffer from problems with your adrenal glands.

Taking other medicines:

If the answer is yes to any of the following questions or you are not sure about the answer, tell your doctor or pharmacist.

- Are you taking any medicine to treat a heart condition e.g. cardiac glycosides or Digoxin?
- Are you taking any tablets or injections for diabetes?
- Are you taking any medicine to reduce cholesterol in your body e.g. Colestyramine?
- Are you taking any medicine for epilespy e.g. Phenytoin or Carbamazepine?
- Are you taking any anticoagulants e.g. Warfarin?
- · Are you taking any contraceptive pills?
- · Are you taking any antidepressants?
- Are you taking any other drugs?

This medicine contains Lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine

If you are unsure, talk to your doctor or pharmacist.

### WHAT PRECAUTIONS SHOULD YOU TAKE:

Do not take more Eltroxin Tablets than your doctor tells you to. Discuss with your doctor or pharmacist if you are worried about anything.

#### **TAKING YOUR MEDICINE:**

- Before starting this treatment, your doctor may record your heart activity
- Your medicine is preferably taken before breakfast, once a day.
   The usual adult starting dose of Eltroxin Tablets is 50 to 100 micrograms for hypothyroidism and in children with myxoedema and hypothyroidism the dose is 25 micrograms daily, which may be
- increased every two to four weeks by 25 micrograms. This dosage may be adjusted depending on the assessment by your doctor.
- Elderly or patients with a heart condition will start on a lower dose that will be adjusted over a number of
- weeks by the doctor.
  Follow the instructions of your doctor regarding dosage.
- Initially your doctor may prescribe a low dose and adjust this to meet your individual needs after taking blood for laboratory analysis of your thyroid function or after assessing your condition.
- Read the label on your medicine container to see how many tablets you should take and when you should take them.
- Swallow the tablets whole with a drink of water.
- Do not take more tablets than your doctor tells you to.
  Do not stop taking your tablets except
- on your doctor's advice. Suddenly stopping this treatment can cause problems such as hypothyroidism to come back or effects on other treatments you may be taking. Your doctor will gradually reduce and stop your treatment over several weeks to avoid these problems.
- If you miss a dose but remember within two or three hours, you can still take that dose. If you miss a dose for longer, miss that dose and take the next one when it is due. Remember that ideally the dose should be taken

#### DO NOT TAKE DOUBLE THE AMOUNT OF TABLETS IF YOU MISS A DOSE

before breakfast.

 If you accidentally take too many Eltroxin Tablets, tell your doctor immediately or contact your nearest Hospital Casualty /Accident and Emergency Department.

#### WHILE TAKING YOUR MEDICINE:

- Be sure to take the tablets as your doctor tells you to.
- Keep taking them until your doctor tells you to stop.
  Your doctor may change your dose
- or your overall condition.
  If you are female and think that you may have become pregnant, tell your doctor.

depending on the result of blood tests

#### AFTER TAKING YOUR MEDICINE:

Eltroxin Tablets may cause unwanted effects in some people. If you experience any of the following, tell your doctor.

- Angina pain (pain in the chest, particularly when taking exercise e.g. walking up hill)
- Irregular heart beats
   Palpitations (loud, thumping heartbeat)
- Muscle cramps or weaknessRapid heart beat
- Diarrhoea & vomitingTremor (shaking)
- Iremor (snaking)
   Restlessness, excitability
- InsomniaHeadaches
- FlushingSweating
- Loss of weight

reduction of dosage or complete withdrawal of treatment, which should be done under medical supervision. If you experience any side effect not listed, discontinue the drug and consult

These side effects usually disappear on

## your physician. PRECAUTIONS:

- Do not store above 25°C.
- Store in original container or package in order to protect from light and
- moisture.

   Keep out of the reach and sight of
- children.
  Do not take the tablets after the 'Expiry Date' printed on the container.
- Return any unused Eltroxin Tablets to your pharmacist who can dispose of them safely for you.

Remember: This medicine is only for you. Only a doctor can prescribe it for you. Never give this medicine to someone else. It could harm them, even if their symptoms seem the same as yours.

#### OTHER USEFUL INFORMATION:

For further information about this product contact Goldshield Pharmaceuticals Ltd., NLA Tower, 12-16 Addiscombe Road, Croydon, Surrey, CR0 0XT, UK.

Date of leaflet revision: August 2006.

10027LF/0199/C 10132LF/0199/C 10133LF/0199/C