PRETENOL-C TABLET

Atenolol/Chlorthalidone (50mg/12.5mg, 100mg/25mg)

What is in this leaflet

- 1. What PRETENOL-C is used for
- 2. How PRETENOL-C works
- 3. Before you use PRETENOL-C
- 4. How to use PRETENOL-C
- 5. While you are using it
- 6. Side effects
- 7. Storage and Disposal of PRETENOL-C
- 8. Product Description
- 9. Manufacturer and Product Registration Holder
- 10. Date of Revision

What PRETENOL-C is used for

PRETENOL-C is used to treat high blood pressure.

How PRETENOL-C works

It contains two different medicines: atenolol and chlorthalidone.

Atenolol belongs to a group of medicines called beta-blockers. It works by making your heart beat more slowly and with less force.

Chlorthalidone belongs to a group of medicines called diuretics. It works by increasing the amount of urine produced by your kidneys.

Before you use PRETENOL-C

- When you must not use it Do not take PRETENOL-C if:

 You are allergic to atendiol or chlorthalidone.

- You are allergic to any of the other ingredients in your medicine.
- You have ever had heart problems
- You have problems with your kidneys.
- You have a tumour called phaeochromocytoma that is not being treated. This is usually near your kidney and can cause high blood pressure.
- You have been told that you have higher than normal levels of acid in your blood (metabolic acidosis).
- You are pregnant, are trying to become pregnant or are breastfeeding.

Do not take PRETENOL-C if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking PRETENOL-C.

- Before you start use it

Check with your doctor or pharmacist before taking PRETENOL-C if:

- You have asthma, wheezing or any other similar breathing problems, or you get allergic reactions, for example to insect stings. If you have ever had asthma or wheezing, do not take this medicine without first checking with your doctor.
- You have a type of chest pain (angina) called Prinzmetal's angina.
- You have poor blood circulation or controlled heart failure.
- You have first-degree heart block.
- You have diabetes. Your medicine may change how you respond to having low blood sugar. You may feel your heart beating faster.
- You have thyrotoxicosis (a condition caused by an overactive thyroid gland). Your medicine may hide the symptoms of thyrotoxicosis.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking PRETENOL-C.

- <u>Taking other medicines</u>

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines. This includes medicines that you buy without a prescription and herbal medicines.

This is because PRETENOL-C can affect the way some other medicines work and some medicines can have an effect on PRETENOL-C.

In particular, tell your doctor if you are taking any of the following medicines:

 Clonidine (for high blood pressure or migraine). If you are taking clonidine and PRETENOL-C together, do not stop taking clonidine unless your doctor tells you to do so. If you have to stop taking clonidine, your doctor

- will give you careful instructions about how to do it.
- Verapamil, diltiazem and nifedipine (for high blood pressure or chest pain).
- Disopyramide or amiodarone (for an uneven heart beat).
- Adrenaline (a medicine that stimulates the heart).
- Ibuprofen or indomethacin (for pain and inflammation).
- Insulin or medicines that you take by mouth for diabetes.
- Lithium (for certain mental illnesses).

How to use *PRETENOL-C*

- How much to use

Always take PRETENOL-C exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults

Pretenol-C 50:

The usual dose for an adult is 1 (one) tablet each day.

Pretenol-C 100:

The usual dose for an adult is half (1/2) tablet each day.

Children

Your medicine must not be given to children.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking PRETENOL-C until your doctor advises you to stop.

- If you forget to use it

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose.

Do not take a double dose to make up for a forgotten dose

- If you use too much (overdose)

If you take more PRETENOL-C than prescribed by your doctor, talk to a doctor or go to a hospital straight away.

Take the medicine pack with you so that the tablets can be identified.

While you are using it

- Things you must do

Tell your doctor immediately if you become pregnant while taking PRETENOL-C.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

If you are having surgery (even at the dentist), tell your doctor or dentist that you are taking PRETENOL-C.

- Things you must not do

Do not stop taking PRETENOL-C without checking with your doctor.

Do not give PRETENOL-C to anyone else, even if they have the same condition as you.

Do not use PRETENOL-C to treat any other complaint unless your doctor tells you to.

- Things to be careful of

Take care driving or operating machinery until you know how PRETENOL-C affects you.

PRETENOL-C may cause dizziness, fatigue, light-headedness or faintness in some people.

Side effects

Like all medicines, PRETENOL-C can cause side effects, although not everybody gets them.

The following listed some of the common side effects:

- Dry mouth.
- Constipation
- Fatigue
- Dizziness

Tell your doctor or pharmacist if you notice anything else 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 calling Tel: 03-78835550, or visiting the website <u>portal.bpfk.gov.my</u> (Consumers → Reporting).

Storage and Disposal of PRETENOL-C

- Storage

Keep your tablets in a cool, dry place where the temperature will stay below 25°C. Protect from light.

Do not keep PRETENOL-C in the bathroom or near a sink.

Do not leave PRETENOL-C in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep this medicine out of reach of children.

A locked cupboard which children cannot reach is a good place to store medicines.

- <u>Disposal</u>

If your doctor tells you to stop using the tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product Description

- What it looks like

PRETENOL-C 50 – A white, 'D'-shaped tablet with marking 'duo862'.

PRETENOL-C 100 – A white, 9mm round tablet, scored on one side and with marking 'd' on another side.

- Ingredients

Active ingredients:

Each PRETENOL-C 50 tablet contains 50mg atenolol and 12.5mg chlorthalidone as the active ingredients.

Each PRETENOL-C 100 tablet contains 100mg atenolol and 25mg chlorthalidone as the active ingredients.

Inactive ingredients:

- Aerosil
- Avicel
- Cornstarch
- Promigel
- Talc
- Lactose
- Tween 80
- Magnesium stearate

- MAL numbers:

PRETENOL-C 50 – MAL19900182A

PRETENOL-C 100 – MAL19900183A

Manufacturer

DUOPHARMA (M) SDN. BHD. (42491-M)

Lot. 2599, Jalan Seruling 59, Kawasan 3, Taman Klang Jaya,

41200 Klang, Selangor Darul Ehsan, Malaysia.

Product Registration Holder

DUOPHARMA (M) SDN. BHD. (42491-M)

Lot. 2599, Jalan Seruling 59, Kawasan 3, Taman Klang Jaya,

41200 Klang, Selangor Darul Ehsan, Malaysia.

Date of Revision

10/04/2014