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APPROVED PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start taking REDORFIN TABLETS.

- Keep this leaflet. You may need to read it again.

- If you have further questions, please ask your doctor or your pharmacist.

- **REDORFIN TABLETS** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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REDORFIN 500 mg TABLETS (Tablet)

REDORFIN 850 mg TABLETS (Tablet)

REDORFIN 1000 mg TABLETS (Tablet)

Metformin hydrochloride

1. WHAT REDORFIN TABLETS CONTAINS

The active substance is metformin hydrochloride.

REDORFIN 500 mg: Each film-coated tablet contains 500 mg metformin hydrochloride equivalent to 390 mg metformin.

REDORFIN 850 mg: Each film-coated tablet contains 850 mg metformin hydrochloride equivalent to 663 mg metformin.

REDORFIN 1000 mg: Each film-coated tablet contains 1 000 mg metformin hydrochloride equivalent to 780 mg metformin.

The other ingredients are magnesium stearate, Opadry YS-1R-7006 and povidone.

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2. WHAT REDORFIN IS USED FOR

REDORFIN is an oral hypoglycaemic medicine used for Type 2 (non-insulin dependent) diabetes mellitus when diet has failed and especially if you are overweight. You can take **REDORFIN** alone as initial therapy, or you can take it in combination with other oral antidiabetic medicines or insulin.

3. BEFORE YOU TAKE REDORFIN TABLETS

Do not take REDORFIN:

- If you are hypersensitive (allergic) to metformin hydrochloride or any of the other ingredients of **REDORFIN**.
- If you have experienced diabetic coma (coma occurring due to diabetic complications),
- If you suffer from diabetic ketoacidosis, a condition with symptoms such as your breath smelling like acetone, nausea, vomiting, excessive thirst and urination and abdominal pain.
- If you have impaired kidney function,
- If you suffer from chronic liver disease,
- If you suffer from acute or chronic diseases such as inflammation of the pancreas, heart or respiratory failure, or if you have experienced a recent heart attack, all of which may cause an inadequate supply of oxygen to the organs.
- If you have a history of, or experience states associated with lactic acidosis such as shock or heart problems which may manifest with symptoms such as nausea, vomiting, heavy and fast breathing, lethargy, fast heart beat and anxiety.
- If you suffer from alcoholism
- If you experience conditions associated with a low level of oxygen in the blood which may manifest with symptoms such as a change in your mental status, shortness of breath, increase in blood pressure, changes in your heart rate and cold hands and feet

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- Do not use in children as safety and efficacy has not been established.
- If you are pregnant and breastfeeding your baby.

Take special care with REDORFIN:

- If you experience lactic acidosis manifested as nausea, vomiting, abdominal pain, lethargy, anxiety, hyperventilation, irregular and fast heart rate, contact your doctor immediately or go to the nearest hospital.
- If you are starting to drink medicines for high blood pressure or if you start drinking anti-inflammatory painkillers such as aspirin or ibuprofen, you should inform your doctor as it may affect your kidney function when taking **REDORFIN** at the same time.
- If you are scheduled to undergo any radiological tests such as x-rays or scans, you should inform your doctor that you are taking **REDORFIN** as you will have to stop taking **REDORFIN** before the test and can only start taking it again in 48 hours or as your doctor determines, depending on your kidney function.
- If you are scheduled to undergo any surgery, you should inform your doctor that you are taking **REDORFIN** as you will have to stop taking it 48 hours before the surgery.
- **REDORFIN** is used for Type 2 diabetes.
- If you are taking **REDORFIN**, your doctor will have to check your vitamin B12 levels every year, since **REDORFIN** may cause mal-absorption of vitamin B12 and folic acid.
- If you are taking other oral anti-diabetic medicines with **REDORFIN**, you should have your blood glucose regularly monitored to prevent hypoglycaemia.
- If you are overweight, you should continue on your energy-restricted diet.
- Your doctor will have to perform regular tests to make sure your kidney function is normal.
- If you are suffering from serious infections, trauma or on a low calorie intake.

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Taking REDORFIN with food and drink:

It is important that you take **REDORFIN** with meals.

Avoid consumption of alcohol and alcohol-containing medications while on treatment with **REDORFIN**.

Pregnancy and breastfeeding:

You should not take REDORFIN if you are pregnant or breastfeeding your baby (see "Do not take **REDORFIN**:")

If you are pregnant or breastfeeding your baby while taking **REDORFIN**, please consult your doctor, pharmacist or other health care professional for advice.

Driving and using machinery:

Take care when driving and using machinery until you know how REDORFIN affects you.

Taking other medicines with REDORFIN:

- If you are taking any medicines used to treat asthma (beta-2-agonists), high blood pressure (diuretics, ACE-inhibitors), allergies or inflammation (glucocorticoids), you must inform your doctor as you will have to undergo more regular blood glucose monitoring.
- If you are taking cimetidine you must inform your doctor as it may affect your kidney function. Your dose of **REDORFIN** would then need to be changed.
- If you are taking warfarin your doctor should be informed as **REDORFIN** may affect the activity of warfarin and your dose of warfarin would then need to be adjusted.
- If you are taking any other oral anti-diabetic medicines you should inform your doctor as it may cause hypoglycaemia if taken together with **REDORFIN**.

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If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **REDORFIN** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

Always take **REDORFIN** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **REDORFIN** is too strong or too weak, talk to your doctor or pharmacist.

Adults: The usual dose is one 500 mg tablet three times a day, or one 1000 mg or 850 mg tablet twice a day, with or after food. Your doctor will prescribe the correct dose for you. After 10-15 days, your doctor may adjust your dose depending on your response to the treatment. Good diabetic control may be achieved within a few days, but it is not unusual for the full effect to be delayed for up to two weeks.
Elderly: Your doctor will adjust your dose based on your kidney function.
Children 12 years and above: The usual starting dose is 500 mg or 850 mg taken once daily, however as with adults the doctor may adjust the dose after 10-15 days.

If you take more REDORFIN than you should:

In excessive doses lactic acidosis manifested as nausea, vomiting, abdominal pain, lethargy, anxiety, hyperventilation, irregular and fast heart rate may occur. If this occurs you should contact your doctor immediately or go to the nearest hospital.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take REDORFIN:

If you forget to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE-EFFECTS

REDORFIN can have side-effects.

If you experience the following side-effects you should report to your doctor or hospital IMMEDIATELY:

- Manifestations of lactic acidosis such as nausea, vomiting, abdominal pain, lethargy, anxiety, hyperventilation, irregular and fast heart rate
- Manifestations of hypoglycaemia such as an irregular heartbeat, clamminess, a feeling of numbness or 'pins and needles', nausea, vomiting, headache, change in mood, weakness, confusion or blurred vision.
- Allergic reactions such as a rash, swelling of the skin, itchiness, sneezing, swelling and redness of eyes, or difficulty breathing.
- Persistent jaundice (yellow discolouration of skin and eyes), and itchy skin which may be as a result of a condition called cholestatic hepatitis.

If you experience the following side-effects you should report to your doctor AS SOON AS POSSIBLE:

- Gastrointestinal side-effects such as nausea, vomiting, constipation, diarrhoea, abdominal pain and a metallic taste in your mouth.
- An allergic reaction.

Not all side effects reported for **REDORFIN** are included in this leaflet. Should your general health worsen while taking **REDORFIN**, please consult your doctor, pharmacist or other health care professional for advice.

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6. STORING AND DISPOSING OF REDORFIN TABLETS

Keep all medicines out of reach of children.

Store at or below 25 °C.

Keep container tightly closed. Keep blisters in outer carton until required for use.

Protect from light and moisture.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF REDORFIN TABLETS

7.1. Blister Pack:

Tablets are packed in clear PVC/PVdC aluminium blister packs:

REDORFIN 500 mg TABLETS: **28's** (2 x 14's), **56's** (4 x 14's), **84's** (6 x 14's)

REDORFIN 850 mg TABLETS: 28's (2 x 14's), **56's** (4 x 14's), **84's** (6 x 14's)

REDORFIN 1000 mg TABLETS: 28's (2 x 14's), **56's** (4 x 14's), **84's** (6 x 14's)

The blister pack is packed in a cardboard carton.

7.2. HDPE Container:

Tablets are packed in a white opaque HDPE container with a white opaque stock ribbed closure and induction sealing wad, in the following pack sizes:

REDORFIN 500 mg TABLETS: 28's, 56's, 84's, 300's, 500's

REDORFIN 850 mg TABLETS: 28's, 56's, 84's, 300's, 500's

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REDORFIN 1000 mg TABLETS: 28's, 56's, 84's, 300's, 500's

No desiccant is included in the container.

The HDPE container is packed in a cardboard carton.

8. IDENTIFICATION OF REDORFIN TABLETS

REDORFIN 500 mg TABLETS:

White, biconvex, circular shaped film-coated tablets with 'A' debossed on one side and '60' debossed on the other side.

REDORFIN 850 mg TABLETS:

White, biconvex, circular shaped film-coated tablets with 'A' debossed on one side and '61' debossed on the other side.

REDORFIN 1000 mg TABLETS:

White, biconvex, oval shaped film-coated tablets with a scoreline in between '6' and '2' on one side and 'A' debossed on the other side.

9. REGISTRATION NUMBER/REFERENCE NUMBER

REDORFIN 500 mg TABLETS: 45/21.2/0204

REDORFIN 850 mg TABLETS: 45/21.2/0205

REDORFIN 1000 mg TABLETS: 45/21.2/0206

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10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

Date of registration:

19 April 2013

Date of revision:

03 November 2022