PATIENT INFORMATION LEAFLET FOR RESCUVOLIN 15 mg TABLETS:

SCHEDULING STATUS:

Tablets: Not scheduled

PROPRIETARY NAME AND DOSAGE FORM:

RESCUVOLIN 15 mg Tablets

Read all of this leaflet carefully because it contains important information for you.
Rescuvolin 15 mg is available without a doctor's prescription, for you to treat a mild illness.
Nevertheless you still need to use Rescuvolin 15 mg carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **Rescuvolin 15 mg** with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

1. WHAT RESCUVOLIN 15 mg CONTAINS:
Each tablet contains calcium folinate equivalent to 15 mg folinic acid.
The other ingredients are: Lactose monohydrate, potato starch, povidone, colloidal silicone dioxide, magnesium stearate.

2. WHAT RESCUVOUN 15 mg IS USED FOR:
Rescuvolin 15 mg contains calcium folinate which is chemically related to a form of vitamin called folic acid. It increases the levels of folic acid in your body.
Rescuvolin 15 mg is given when levels of folic acid in the body are reduced during treatment with high doses of methotrexate. Methotrexate is a medicine used to treat cancer and it can lower your body's levels of folic acid. This use of **Rescuvolin 15 mg** is known as 'calcium leucovorin rescue'.

3. BEFORE YOU TAKE RESCUVOLIN 15 mg:

Do not take Rescuvolin 15 mg if:

- you are hypersensitive (allergic) to calcium folinate or any of the other ingredients of **Rescuvolin 15 mg**
- you suffer from stomach and bowel complaints (vomiting and diarrhoea).

Take special care with Rescuvolin 15 mg:
Do not take **Rescuvolin 15 mg** if you have anemia that is caused by a lack of vitamin B12.

Tell your doctor before you use **Rescuvolin 15 mg**, if you currently have, or have had anaemia that needed treatment.

Pregnancy and Breastfeeding:
If you are pregnant or breastfeeding your baby while taking **Rescuvolin 15 mg**, please consult your doctor, pharmacist or other healthcare professional for advice.

Driving and using machinery:
Rescuvolin 15 mg is not expected to affect your ability to drive or use machines.

Important information about some of the ingredients of Rescuvolin 15 mg:
Rescuvolin 15 mg tablets contain lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

Taking other medicines with Rescuvolin 15 mg:
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

- **Rescuvolin 15 mg** can reduce the effectiveness of medicines used to treat epilepsy (phenobarbital, phenytoin or primidone) and lead to more frequent seizures (fits).
- **Rescuvolin 15 mg** may increase the side effects of fluorouracil (medicine used to treat cancer).

4. HOW TO TAKE RESCUVOUN 15 mg:
Do not share medicines prescribed for you with any other person.

Always take **Rescuvolin 15 mg** as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
Rescuvolin 15 mg tablets should be taken orally.

The dose of **Rescuvolin 15 mg** you take will vary depending on the dose of methotrexate you were given.
To be **sure Rescuvolin 15 mg** is helping your condition, your blood will need to be tested often. This will help your doctor determine how long to treat you with **Rescuvolin 15 mg**.
If too much methotrexate has been given, the dose of **Rescuvolin 15 mg** should be the same as, or more than the dose of methotrexate given, and should be given within forty-eight hour after the start of you receiving methotrexate. You will be closely monitored during the treatment.
If you take more **Rescuvolin 15 mg** than you should:

If you take more Rescuvolin 15 mg thank you should:
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

5. POSSIBLE SIDE EFFECTS:

Rescuvolin 15 mg can have side effects.

Not all side effects reported for **Rescuvolin 15 mg** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **Rescuvolin 15 mg**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happen, stop taking **Rescuvolin 15 mg** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Sudden wheeziness or difficulty in breathing,
- Swelling of eyelids, face, tongue, throat or lips,
- Rash or itching (especially affecting the whole body).

These are all very serious side effects. If you have them, you have had a serious allergic reaction to **Rescuvolin 15 mg**. You may need urgent medical attention or hospitalisation.

You should tell your doctor immediately or go to the casualty department at your nearest hospital if you begin having seizures. This is a serious side effect. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- Nausea (feeling sick)
- Diarrhoea

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF RESCUVOLIN 15 mg:

Store all medicines out of reach and sight of children.
Store at or below 25 °C and protect from light.
Store in the original carton until ready for use, in order to protect from light.
Do not use after the expiry date stated on the label.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF RESCUVOLIN 15 mg:

Bottles containing 10 tablets, or blister strips containing 10 tablets.
The blister strips are packed into an outer cardboard carton.

8. IDENTIFICATION OF RESCUVOLIN 15 mg:

Each tablet is cream-coloured, flat-faced and scored.

9. REGISTRATION NUMBER/REFERENCE NUMBER:

RESCUVOLIN 15 mg Tablets: S/22.1.4/339

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Teva Pharmaceuticals (Pty) Ltd
Suite 1, Building 4
Ruimsig Office Park
Hole in One Road
Ruimsig, Roodepoort

11. DATE OF PUBLICATION:

Date on the registration certificate:
03 November 1987

Date of most recently revised package insert: 28 November 2014