

Quatrefolic®

Primary biologically active form of folate / Levomefolic acid

Consumer Medicine Information

1. What is in the leaflet?

This leaflet answers some of the more common questions about Quatrefolic® capsules.

It does not contain all the available information. It does not take the place of talking to your healthcare professional.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Quatrefolic® capsules against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your healthcare professional.

Keep this leaflet with the medicine.

You may need to read it again.

2. What Quatrefolic® is used for

Quatrefolic® contains levomefolic acid which is a form of biologically active folate, 5-methyltetrahydrofolate (5-MTHF).

Dietary folate and synthetic folic acid are not biologically active and need to be converted into 5-MTHF in a multistep process, requiring the enzyme methylenetetrahydrofolate reductase (MTHFR). Individuals with polymorphic forms of this enzyme cannot convert adequate amounts of biologically active folate. 5-MTHF can bypass the MTHFR enzyme to meet nutritional demands. Folate is essential for DNA synthesis, cell division, red blood cell production and homocysteine metabolism. Demands for folate increase during pregnancy due to increased requirements for foetal growth and development.

Your healthcare professional may have prescribed Quatrefolic® for another reason.

Ask your healthcare professional if you have any questions concerning why Quatrefolic® has been prescribed for you. Quatrefolic® is not addictive.

3. Before you take Quatrefolic®

Vitamin supplements should not replace a balanced diet.

If symptoms persist consult your healthcare professional.

Do not take while on warfarin therapy.

Do not exceed the stated dose except on medical advice. If you have had a baby with a neural tube defect/spina bifida, seek specific medical advice.

Do not take Quatrefolic® if:

- You have had an allergic reaction to Quatrefolic®, or any ingredient in Quatrefolic® (listed in section 8).**
- The safety seal is broken, missing or shows signs of tampering.**
- The expiry date (EXP) printed on the pack has passed.**
If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure you should start taking Quatrefolic® contact your healthcare professional.

Before you take Quatrefolic®, tell your doctor if:

- You have any allergies to any other medicines, foods, preservatives, dyes or additives.**
If you experience any allergic reaction or other side effects after consuming Quatrefolic® you should discontinue use and consult with your healthcare professional.
- You are pregnant or planning to become pregnant.**
- You are breastfeeding or planning to breastfeed.**
- You have or have had any other health problems or issues including:**
Iron deficiency (anemia) or think that you might be anemic.
- You drink large amounts of alcohol.**
- You are taking other medicines.**

Tell your healthcare professional if you are taking any other medicines, including any that you get without a prescription.

Some medicines may be affected by Quatrefolic®, or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your healthcare professional has more information on medicines to be careful with or avoid while taking Quatrefolic®.

If you have not told your healthcare professional about any of the above, tell them before you start taking

4. How to take Quatrefolic®

- Follow all directions given to you by your healthcare professional carefully.**
- Take Quatrefolic® exactly as your healthcare professional has prescribed.**
This may differ from the information contained in this leaflet.
- How much Quatrefolic® should be taken?**
One (1) capsule a day. Do not exceed the stated dose.
- How to take Quatrefolic®**
Capsules should be swallowed whole. Do not take any capsules that are damaged.
- How long to take Quatrefolic®**
Take Quatrefolic® as long as your healthcare professional prescribes.
- If you forget to take Quatrefolic®**
Do not try to make up for missed doses by taking an extra dose. This may increase the chance of experiencing an unwanted side effect.
Do not exceed the stated dose.
If it is almost time for your next dose, skip the dose you missed and take the next dose when you are supposed to.
If you are unsure of what to do, check with your healthcare professional.
- If you have taken too much Quatrefolic® (overdose)**
Please visit your healthcare professional if there are signs of discomfort. Tell them how much Quatrefolic® you took and they will determine what action is best for your health.

5. While you are taking Quatrefolic®

Things you MUST do:

- If you become pregnant while taking Quatrefolic®, tell your healthcare professional immediately.**
- If you are about to start taking a new medicine, tell your healthcare professional that you are taking Quatrefolic®.**
- If you are planning to have surgery, including dental surgery, tell your healthcare professional that you are taking Quatrefolic®.**
- Always follow your healthcare professional's instructions carefully.**

Things you MUST NOT do:

- Do not heat Quatrefolic® or add into hot foods.
- Do not expose Quatrefolic® to extreme heat conditions for extended periods of time.
- Do not exceed the stated daily dose.

6. Side Effects

Quatrefolic® has low risk of side effects when taken as directed.

Ask your healthcare professional to answer any questions you may have.

However, get medical help right away if you notice any symptoms of a serious allergic reaction, including:

- rash
- itching/swelling (face/tongue/throat)
- dizziness
- trouble breathing.

These side effects are usually mild and dose related. Most of them disappear completely in a few days to a few weeks after the dose of Quatrefolic® is lowered or stopped.

Tell your doctor if you notice anything else that is making you feel unwell.

7. After taking Quatrefolic®

Storage

Keep Quatrefolic® in its bottle until it is time to take it. If you take the capsules out of the bottle they may not keep well.

Store Quatrefolic® below 30°C.

Do not store Quatrefolic®, or any other medicine, in a bathroom or near a sink. Do not leave it in the car or on a window sill.

Heat and dampness can destroy the medicine.

Protect Quatrefolic® from light.

Keep out of the reach of children

8. Product description

What Quatrefolic® looks like:

Quatrefolic® is a hard clear capsule. Quatrefolic® is packed in a recyclable bottle with a safety seal over the cap. Quatrefolic® is available in bottles containing 60 capsules.

Ingredients:

Active Ingredients PER capsule:
Levomefolic acid 0.926 mg
Equiv. Levomefolic acid 500 µg

Excipient Ingredients:

- Cellulose

- Hypromellose
- Silica
- Magnesium stearate

Quatrefolic® is suitable for vegetarians

Quatrefolic® is dairy and gluten free

9. Translation

Not available

10. Manufacturer

Quatrefolic® is supplied in Australia by:

Medlab Clinical Limited™

66 McCauley Street

Alexandria NSW 2015

Toll free: 1300 369 570

Quatrefolic® is covered by US patent No 7,947,662 and it is a registered trademark of Gnosis S.p.a.

Australian Listing Number

AUST L 287400

This Leaflet was prepared in Aug 2017

Medlab Clinical Limited™