

Package leaflet: Information for the user

# Aqualibra®

80 mg/90 mg/180 mg film-coated tablets

Dried extract of restharrow root (5-8:1)  
Dried extract of Orthosiphon leaves (5-7:1)  
Dried extract of goldenrod (4-7:1)

For use in adults and children over 12 years.



**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 5 days.

## What is in this leaflet

1. What Aqualibra® is and what it is used for
2. What you need to know before you take Aqualibra®
3. How to take Aqualibra®
4. Possible side effects
5. How to store Aqualibra®
6. Contents of the pack and other information

## 1. WHAT AQUALIBRA® IS AND WHAT IT IS USED FOR

Aqualibra® is a herbal medicine used to flush out the urinary tract.

Aqualibra® is used to flush out the urinary tract in the event of bacterial and inflammatory diseases. Bladder cleansing to prevent and treat kidney stones and kidney sludge.

You must consult a doctor if you see blood in your urine, in the event of fever, or if symptoms persist beyond 5 days.

## 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE AQUALIBRA®

**Do not take Aqualibra®:**

- if you are allergic to restharrow root, Orthosiphon leaves, goldenrod, or any of the other ingredients of this medicine (listed in section 6).
- if you have water accumulation in tissue (oedema) due to impaired heart or kidney function.

## Warnings and precautions

Talk to your doctor or pharmacist before taking Aqualibra®.

## Children and adolescents

There are no adequate studies of the use of Aqualibra® in children. For this reason, the medicine should not be used in children under 12 years of age.

## Other medicines and Aqualibra®

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

## Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Aqualibra® should not be taken during pregnancy and breast-feeding due to insufficient evidence.

## Driving and using machines

Aqualibra® has no effect on these activities.

## Aqualibra® contains lactose and glucose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Aqualibra®.

## 3. HOW TO TAKE AQUALIBRA®

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults and children over 12 years should take 2 Aqualibra® film-coated tablets three times daily with plenty of water.

The film-coated tablets should be swallowed whole. Tablets can be taken with or without food. Aqualibra® must always be taken with plenty of water. Please also ensure ample fluid intake (at least 2 litres per day) throughout the duration of the treatment.

The duration of use is in general not restricted, but depends on the type, severity and course of the disease. The duration of use is to be determined by a doctor. In all cases, please keep in mind the information in section 1 and section 4.

Please talk to your doctor or pharmacist if you feel that the effect of Aqualibra® is too strong or too weak.

**If you take more Aqualibra® than you should**

There are to date no known cases of poisoning as the result of Aqualibra®. If excessive amounts of Aqualibra® are taken, the symptoms described in section 4 may be intensified. In this case, please contact a doctor. The doctor will be able to decide if any further measures are necessary. If you experience increased urination, this must be balanced with adequate fluid intake.

**If you forget to take Aqualibra®**

Do not take a double dose to make up for a forgotten dose. You should not take more than 6 film-coated tablets per day.

**If you stop taking Aqualibra®**

There are no known adverse effects.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very rare (fewer than 1 in 10,000 patients treated)

- Gastrointestinal symptoms (nausea, vomiting, diarrhoea)
- Hypersensitivity reactions (rash, itching)

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the reporting system at the Bundesinstitut für Arzneimittel und Medizinprodukte [German Federal Office for Drugs and Medical Devices (BfArM)], Abt. Pharmakovigilanz [Pharmacovigilance Department], Kurt-Georg-Kiesinger Allee 3, 53175 Bonn, website: <http://www.bfarm.de>. By reporting side effects you can help provide more information on the safety of this medicine.

**5. HOW TO STORE AQUALIBRA®**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and the carton after "Expiry date". The expiry date refers to the last day of that month.

Do not store above 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**6. CONTENTS OF THE PACK AND OTHER INFORMATION**

**What Aqualibra® contains**

The active substances are:

- 80 mg dried extract of restharrow root (5-8:1), extraction agent: water
- 90 mg dried extract of Orthosiphon leaves (5-7:1), extraction agent: water
- 180 mg dried extract of goldenrod (4-7:1), extraction agent: water

The other ingredients are:

Povidone K30, crospovidone, colloidal silica, microcrystalline cellulose, magnesium stearate, talc, macrogol 3000, polyvinyl alcohol, lactose monohydrate, spray dried glucose syrup (Ph. Eur.), maltodextrin, titanium dioxide, chlorophyll copper complex

**What Aqualibra® looks like and contents of the pack**

1 pack contains 60 dark green, round film-coated tablets.

**Pharmaceutical company and manufacturer**

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Unofficial translation of the German package leaflet.

