

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

SACHET FOR 2 G GRANULES

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

BindRen 2 g granules
colestilan
Oral use

2. METHOD OF ADMINISTRATION

Read the package leaflet before use.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

2 g

6. OTHER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

SACHET FOR 3 G GRANULES

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

BindRen 3 g granules
colestilan
Oral use

2. METHOD OF ADMINISTRATION

Read the package leaflet before use.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

3 g

6. OTHER

Medicinal product no longer authorised

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON FOR BOTTLES – FILM-COATED TABLETS

1. NAME OF THE MEDICINAL PRODUCT

BindRen 1 g film-coated tablets
colestilan

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 1 g colestilan.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

45 film-coated tablets
99 film-coated tablets
198 film-coated tablets
270 film-coated tablets
297 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Keep the bottle tightly closed in order to protect from moisture.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Mitsubishi Tanabe Pharma Europe Ltd.
Dashwood House
69, Old Broad Street
London
EC2M 1QS
United Kingdom

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/12/804/001-005

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE**16. INFORMATION IN BRAILLE**

BindRen 1 g tablets

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

BOTTLE LABEL – FILM-COATED TABLETS

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BindRen 1 g film-coated tablets
colestilan

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 1 g colestilan.

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99 film-coated tablets
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Read the package leaflet before use.
Oral use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

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B. PACKAGE LEAFLET

Medicinal product no longer authorised

Package leaflet: Information for the patient

BindRen 1 g film-coated tablets colestilan

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What BindRen is and what it is used for

BindRen contains the active substance colestilan. It is used to lower high blood phosphorus levels in adult patients undergoing dialysis due to poor kidney function.

About high blood phosphorus levels (hyperphosphataemia)

If your kidneys no longer function properly you may undergo dialysis, which replaces many of the functions of your kidneys. You have also been advised to follow a special diet to reduce the amount of phosphorus that your body takes from food. Sometimes, the dialysis and diet are not enough to stop the phosphorus in your blood rising to high levels, a condition referred to by your doctor as hyperphosphataemia. Keeping the phosphorus level in your blood low is important to maintain healthy bones and blood vessels and to prevent itchy skin, red eyes, bone pain or bone fractures.

How BindRen works

Colestilan binds to the phosphorus from food in your digestive tract to prevent it from being absorbed into your blood. The colestilan-bound phosphorus is then excreted from your body in faeces. However, even though you are taking BindRen, you must also follow the special diet recommended by your doctor.

2. What you need to know before you take BindRen

Do not take BindRen

- if you are allergic to colestilan or any of the other ingredients of this medicine (listed in section 6)
- if you have bowel obstruction (a blockage of your intestines)

Warning and precautions

Talk to your doctor or pharmacist before taking BindRen if you are suffering from any of the following problems, since this medicine may not be right for you:

- swallowing problems
- severe problems with stomach or bowel movement, such as constipation, ulcers in the stomach or the gut or haemorrhoids, since these problems may lead to increased risk of e.g. bleeding from the intestines
- recent major stomach or bowel surgery
- gall bladder obstruction
- severe liver problems
- seizures
- recent history of inflammation of the membrane that forms the lining of the abdominal (tummy) cavity (peritonitis)
- low levels of albumin (a protein) in your blood

Talk to your doctor or pharmacist if during your treatment with BindRen, any of the following applies to you:

- you experience constipation, since your doctor may wish to monitor your bowel function to detect potential side effects (see section 4).
- you have been told that you have a disorder that decreases the intestines ability to absorb nutrients (malabsorption syndrome) or if you are treated with so called coumarin anticoagulants (e.g. warfarin), since your doctor may want to monitor your blood and possibly ask you to start taking vitamin supplements.
- you have abnormally low levels of calcium in your blood. BindRen does not contain calcium and your doctor may prescribe additional calcium tablets.
- you have abnormally high levels of calcium in your blood due to overactivity of the parathyroid glands. BindRen alone cannot treat this condition and other medicines should be prescribed for you.

Children and adolescents

No data are available on the safety and effectiveness of BindRen in children and adolescents (below the age of 18 years). BindRen should not be used in children and adolescents.

Other medicines and BindRen

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines for irregular heart rhythm (such as digoxin), for treating high blood pressure (such as enalapril maleate), anti-seizure medicines (such as valproic acid, phenytoin, carbamazepine, lamotrigine, oxcarbazepine, topiramate, gabapentin, vigabatrin, zonisamide and levetiracetam), levothyroxine (used to treat thyroid hormone deficiency), oral birth control medicines (oestrogen, progestogen or combination pills), immune system suppressing medicines (such as cyclosporine, mycophenolate mofetil, tacrolimus). This is because your doctor may want to monitor your health, change the dose of BindRen or the other medicine you are taking or tell you to not take BindRen and the other medicine at the same time.

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 for advice before taking this medicine. If you do become pregnant or you are breast-feeding, and your doctor decides that you should continue your treatment with BindRen, your doctor may ask you to also take vitamin supplements.

Driving and using machines

BindRen has no or negligible influence on the ability to drive or use machines.

3. How to take BindRen

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

Manufacturer

allphamed PHARBIL Arzneimittel GmbH
Hildebrandstr. 12
37081 Göttingen
Germany

For more information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

Deutschland, Österreich

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This leaflet was last revised in**Other sources of information**

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>