before taking this medicine:

- If you answer YES to any of these questions tell your doctor or pharmacist

Your medicine will be referred to as Salazopyrin EN tablets throughout the following leaflet.

In this leaflet:

1. What Salazopyrin EN tablets are and what they are used for
2. Before you take Salazopyrin EN tablets
3. How to take Salazopyrin EN tablets
4. Possible side effects
5. How to store Salazopyrin EN tablets
6. Further information

Read all of this leaflet carefully before you take this medicine:

- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It
- This leaflet contains important information about your medicine.
- It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not
- Please tell your doctor or pharmacist if you are taking or have recently

1. WHAT SALAZOPYRIN EN TABLETS ARE AND WHAT THEY ARE USED FOR

The main forms of inflammatory bowel disease are Ulcerative Colitis and Crohn's disease. Although the diseases have some features in common, there are some important differences.

Ulcerative Colitis is an inflammatory disease which affects only the large bowel (colon and back passage). Crohn's disease may affect the digestive system from the mouth to the anus, but it most commonly

The tablets should be taken with a glass of water and should be swallowed

If you miss a dose of Salazopyrin EN tablets

- If you forget to take a dose, just take the next dose as usual. Do not double

If you are pregnant or breast-feeding, think you may be pregnant or are

- To avoid problems with your kidneys.

If you are a child and have arthritis?

- Your doctor will tell you what dose your child will need to use. This will be

This medicine has been prescribed for you. Do not pass it on to others. It

3. HOW TO TAKE SALAZOPYRIN EN TABLETS

- Ensure that you drink adequate fluids whilst you are taking this

Inflammatory bowel disease

The main forms of inflammatory bowel disease are Ulcerative Colitis and Crohn's disease. Although the diseases have some features in common, there are some important differences.

Ulcerative Colitis is an inflammatory disease which affects only the large bowel (colon and back passage). Crohn's disease may affect the digestive system from the mouth to the anus, but it most commonly

Inflammatory bowel disease


3. HOW TO TAKE SALAZOPYRIN EN TABLETS

The tablets should be taken with a glass of water and should be swallowed

If you are a child and have arthritis?

- Your doctor will tell you what dose your child will need to use. This will be

This medicine has been prescribed for you. Do not pass it on to others. It

3. HOW TO TAKE SALAZOPYRIN EN TABLETS

The tablets should be taken with a glass of water and should be swallowed

If you are a child and have arthritis?

- Your doctor will tell you what dose your child will need to use. This will be

This medicine has been prescribed for you. Do not pass it on to others. It

3. HOW TO TAKE SALAZOPYRIN EN TABLETS

The tablets should be taken with a glass of water and should be swallowed

If you are a child and have arthritis?

- Your doctor will tell you what dose your child will need to use. This will be

This medicine has been prescribed for you. Do not pass it on to others. It

3. HOW TO TAKE SALAZOPYRIN EN TABLETS

The tablets should be taken with a glass of water and should be swallowed

If you are a child and have arthritis?

- Your doctor will tell you what dose your child will need to use. This will be

This medicine has been prescribed for you. Do not pass it on to others. It

3. HOW TO TAKE SALAZOPYRIN EN TABLETS

The tablets should be taken with a glass of water and should be swallowed

If you are a child and have arthritis?

- Your doctor will tell you what dose your child will need to use. This will be

This medicine has been prescribed for you. Do not pass it on to others. It

3. HOW TO TAKE SALAZOPYRIN EN TABLETS

The tablets should be taken with a glass of water and should be swallowed

If you are a child and have arthritis?

- Your doctor will tell you what dose your child will need to use. This will be

This medicine has been prescribed for you. Do not pass it on to others. It

3. HOW TO TAKE SALAZOPYRIN EN TABLETS

The tablets should be taken with a glass of water and should be swallowed

If you are a child and have arthritis?

- Your doctor will tell you what dose your child will need to use. This will be

This medicine has been prescribed for you. Do not pass it on to others. It

3. HOW TO TAKE SALAZOPYRIN EN TABLETS

The tablets should be taken with a glass of water and should be swallowed
By reporting side effects, you can help provide more information on the safety of this medicine. Reporting of side effects includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

If you get any side effects, talk to your doctor, pharmacist or nurse. This may help prevent further problems with this medicine. Reporting of side effects helps the manufacturers and the medical men and women who use this medicine to improve it. It also helps others who take this medicine.

Common side-effects which may affect more than 1 person in 100 are listed below:

- Dizziness
- Difficulty in sleeping
- Headache
- Changes in taste
- Abdominal pains
- Diarrhoea
- Being sick
- Ringing in the ears
- Blood shot eyes
- Inflamed mouth (stomatitis)
- Cough
- Itching of the skin
- Joint pain
- Proton in urine
- Fever

Uncommon side-effects which may affect more than 1 person in 100 are listed below:

- Depression
- Fits, jerky, uncontrolled movements
- Loss of balance
- Shortness of breath
- Hair loss
- Hives
- Puffiness around the eyes and face

Since introduction to the market the following side-effects have been reported:

- Inflammation of the lining of the brain
- Severe diarrhoea
- Other blood disorders including anaemia, enlarged glands (lymph nodes)
- Blood vessel inflammation
- Loss of appetite
- Hallucinations
- Changes in mental state
- Changes in smell
- Inflammation of the sac surrounding the heart (pericarditis)
- Inflammation of the heart muscle (myocarditis)
- Blush tint to skin due to poor circulation
- Lung complications with breathlessness
- Inflammation of the salivary glands on either side of the face
- Kidney inflammation and kidney pain,
- Liver disease (hepatitis)
- Yellowing of the skin or whites of the eyes (jaundice)
- Inflammation of pancreas, which causes severe pain in the abdomen and face
- Rash, reddening or blistering of the skin, eczema,
- Tingling, numbness, pain in hands and feet
- Blood in urine
- Urine or motions may become a yellow/orange colour
- Itching of the skin
- Cough
- Protein in urine
- Headache
- Difficulty sleeping
- Dizziness

Other side-effects that may occur are:

- Indigestion, heartburn
- Feeling sick (nausea)

Since introduction to the market the following side-effects have been reported:

- Temporary infertility in men. Fertility returns when treatment is stopped.
- Very rarely sulfasalazine has caused permanent staining of extended wear soft contact lenses. (See section 6 General Advice for further information).

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side-effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

If reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE SALAZOPYRIN EN TABLETS
Check the “expiry” date, which is printed on the carton label and bottle label. If it is out of date do not use it and contact your pharmacist.

Keep out of the sight and reach of children. If your doctor decides to stop the treatment return any left over medicine to the pharmacist. Only keep them if your doctor tells you.

If your tablets become discoloured or shown any other signs of deterioration, please contact your doctor before taking your medicine.

6. FURTHER INFORMATION
What Salazopyrin EN tablets contain
Each gastro-resistant tablet contains 500mg sulfasalazine as the active ingredient. Other ingredients: maize starch pregelatinised, magnesium stearate, colloidal anhydrous silicon dioxide, celullose acetate phthalate, propylene glycol, white bees wax, camaba wax, glyceryl monostearate self-emulsifying, macrogel 20000 and talc.

What Salazopyrin EN tablets looks like and contents of the pack
Salazopyrin EN tablets are yellow film-coated, ovoid gastro-resistant tablets embossed “99” on one side and “102” on the other. They are coated with a film, which stops them breaking up until they leave the stomach. The tablets are the colour of the medicine itself. They contain no artificial colouring.

Salazopyrin EN tablets comes in bottle containing 100 tablets.

Manufacturer and Product Licence Holder
Manufactured by Kemwell AB, Bjorkgatan 30, SE-75182 Uppsala, Sweden. Procured from within the EU by Product Licence holder Star Pharmaceuticals Ltd, 5 Sandridge Close, Harrow Middlesex, HA1 1XQ. Repackaged by Servipharm Ltd.

General Advice
Because the tablets are coloured yellow they may cause your urine or motions to become a yellow/orange colour. This is normal and harmless but can stain fabric. Any Salazopyrin soiled fabric should be put in to soak. Difficult stains may be removed with a solution of washing soda. Always test the effect of soda on a small piece of the fabric first. Then apply a mild acid such as white vinegar.

Sulfasalazine has caused permanent staining of extended wear soft contact lenses. Although this happened very rarely. Daily-wear soft contact lenses and gas permeable lenses respond to standard cleaning if this happens.

Where can I get more advice about Ulcerative Colitis and Crohn’s Disease?
The National Association for Colitis and Crohn’s Disease (NACC) has local groups which offer meetings, events and information for patients. They may be contacted at NACC, P.O. Box 205, St. Albans, Herts, AL1 1AB.

Leaflet revision and issue date (Ref) 13.06.14[5]
Salazopyrin is a trademark of Pfizer Health AB.
Sulfasalazine 500mg gastro-resistant tablets

PATIENT INFORMATION LEAFLET

Your medicine will be referred to as Sulfasalazine tablets throughout the following leaflet.

In this leaflet:
1. What Sulfasalazine Tablets are and what they are used for
2. Before you take Sulfasalazine tablets
3. How to take Sulfasalazine tablets
4. Possible side effects
5. How to store Sulfasalazine tablets
6. Further information

Read all of this leaflet carefully before you take this medicine - Keep this leaflet. You may need to read it again. - If you have any further questions, ask your doctor or pharmacist. - This medicine has been prescribed for you. Do not pass it on to others. It may not be used if some of the side effects are the same as yours. - If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

1. WHAT SULFASALAZINE TABLETS ARE AND WHAT THEY ARE USED FOR

The active substance in Sulfasalazine tablets is sulfasalazine, which is an anti-inflammatory drug and belongs to a group of medicines called aminosalicylates. Your doctor may give you Sulfasalazine tablets to treat and manage inflammatory bowel disease to treat rheumatoid arthritis.

Inflammatory bowel disease

The main forms of inflammatory bowel disease are Ulcerative Colitis and Crohn’s disease. Although they are very similar, there are some important differences.

Ulcerative Colitis is an inflammatory disease which affects only the large bowel (colon and back passage). The lining of the bowel becomes inflamed and painful.

Crohn’s disease is an inflammatory disease, which may affect any part of the digestive system from the mouth to the anus, but it mostly commonly affects the last part of the small bowel and the first part of the large bowel. Symptoms include abdominal pain and diarrhoea (which may be bloody).

Sulfasalazine tablets are used to control the flare-ups of ulcerative colitis. They may also be used at lower doses to prevent more flare-ups of ulcerative colitis.

Crohn’s disease is an inflammatory disease which affects any part of the digestive system from the mouth to the anus, but it most commonly affects the last part of the small bowel and the first part of the large bowel. Symptoms include abdominal pain and diarrhoea (which may be bloody).

2. BEFORE YOU TAKE SULFASALAZINE TABLETS

Your doctor will perform complete blood counts and liver function tests before starting Sulfasalazine tablets and every second week during the first three months of therapy. During the second three months, the same tests should be performed once or twice a month. Your doctor will also test your urine for protein and blood. Urine analysis and an assessment of kidney function must be performed before starting Sulfasalazine tablets and at regular intervals. They may also test your urine for protein and blood.

Sulfasalazine tablets are not to be used in children under 2 years of age.

Take special care with Sulfasalazine tablets

If you answer YES to any of these questions tell your doctor or pharmacist before taking this medicine:

- Have you been told by your doctor that you have an inherited condition in which you make an enzyme known as glucose-6- dehydrogenase which helps red blood cells function normally? - Have you ever had jaundice?

- If you are a child and have arthritis?

3. HOW TO TAKE SULFASALAZINE TABLETS

The tablets should be taken with a glass of water and should be swallowed whole. Do not chew, break or crush the tablets.

The tablets may be taken whole. Do not crush, break or chew the tablets.

Driving and using machines

Sulfasalazine tablets are unlikely to affect your ability to drive or use machinery.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Sulfasalazine tablets can cause side effects, although not everybody gets them.

4.1 Common side effects

These symptoms are usually very rare but can be serious. If you experience any of the following symptoms after taking this medicine.

- Stop taking Sulfasalazine tablets and tell your doctor immediately if you experience any of the following symptoms after taking this medicine.
- If you have a skin condition with a rash (usually confined to the cheeks and bridge of the nose) peeling skin or blistering. It may be difficult to tell whether a rash is due to this medicine or to another cause; do not stop taking this medicine, avoid strong sunlight and contact your doctor promptly.
- If you have a skin condition with a rash (usually confined to the cheeks and bridge of the nose) peeling skin or blistering. It may be difficult to tell whether a rash is due to this medicine or to another cause; do not stop taking this medicine, avoid strong sunlight and contact your doctor promptly.

Stop taking Sulfasalazine tablets and tell your doctor immediately if you experience any of the following symptoms after taking this medicine. This is to avoid problems with your kidneys.

- If you take more Sulfasalazine tablets than you should Contact your hospital casualty department. It may be your doctor, immediately if you have taken too many tablets (an overdose) or if a child has taken medicine.
- Please take this leaflet and these tablets with you to the hospital casualty department or to your doctor.

If you miss a dose of Sulfasalazine tablets

- If you take more Sulfasalazine tablets than you should Contact your hospital casualty department. It may be your doctor, immediately if you have taken too many tablets (an overdose) or if a child has taken medicine.

The tablets should be taken whole. Do not crush, break or chew the tablets.

Morning

1st Week
2nd Week
3rd Week
4th Week

Evening

- *If* to a maximum of 6 tablets per day.
- Do not take more than 6 tablets a day.
- Children - No recommendations.

How long should you use these tablets?

How long you use these tablets depends on how well the tablets suit you.

Inflammatory bowel disease

- Ulcerative Colitis and Crohn’s Disease

- Adults and the Elderly

- Severe Flare-Ups - 2-4 tablets four times a day, with other medicines such as corticosteroids and following morning dose. Mild/Moderate Flare-Ups - 2-4 tablets four times a day, but not always with other medicines.

Children 2 years of age and over - Your doctor will tell you what dose your child will need to use. This will be based on your child’s weight.

Rheumatoid arthritis

- Adults and the Elderly - Start on one tablet each day for the first week. Then, increase the dose by one tablet a day each week to a maximum of 6 tablets daily as shown in table.

Morning

1st Week
2nd Week
3rd Week
4th Week

Evening

- *If* to a maximum of 6 tablets per day.
- Do not take more than 6 tablets a day.
- Children - No recommendations.

How long should you use these tablets?

How long you use these tablets depends on how well the tablets suit you.

- Ulcerative Colitis and Crohn’s Disease

- Adults and the Elderly

- Severe Flare-Ups - 2-4 tablets four times a day, with other medicines such as corticosteroids and following morning dose. Mild/Moderate Flare-Ups - 2-4 tablets four times a day, but not always with other medicines.

Children 2 years of age and over - Your doctor will tell you what dose your child will need to use. This will be based on your child’s weight.

Rheumatoid arthritis

- Adults and the Elderly - Start on one tablet each day for the first week. Then, increase the dose by one tablet a day each week to a maximum of 6 tablets daily as shown in table.

Morning

1st Week
2nd Week
3rd Week
4th Week

Evening

- *If* to a maximum of 6 tablets per day.
- Do not take more than 6 tablets a day.
- Children - No recommendations.

How long should you use these tablets?

How long you use these tablets depends on how well the tablets suit you.

Inflammatory bowel disease

- Ulcerative Colitis and Crohn’s Disease

- Adults and the Elderly

- Severe Flare-Ups - 2-4 tablets four times a day, with other medicines such as corticosteroids and following morning dose. Mild/Moderate Flare-Ups - 2-4 tablets four times a day, but not always with other medicines.

Children 2 years of age and over - Your doctor will tell you what dose your child will need to use. This will be based on your child’s weight.

Rheumatoid arthritis

- Adults and the Elderly - Start on one tablet each day for the first week. Then, increase the dose by one tablet a day each week to a maximum of 6 tablets daily as shown in table.

Morning

1st Week
2nd Week
3rd Week
4th Week

Evening

- *If* to a maximum of 6 tablets per day.
- Do not take more than 6 tablets a day.
- Children - No recommendations.

How long should you use these tablets?

How long you use these tablets depends on how well the tablets suit you.

Inflammatory bowel disease

- Ulcerative Colitis and Crohn’s Disease

- Adults and the Elderly

- Severe Flare-Ups - 2-4 tablets four times a day, with other medicines such as corticosteroids and following morning dose. Mild/Moderate Flare-Ups - 2-4 tablets four times a day, but not always with other medicines.

Children 2 years of age and over - Your doctor will tell you what dose your child will need to use. This will be based on your child’s weight.

Rheumatoid arthritis

- Adults and the Elderly - Start on one tablet each day for the first week. Then, increase the dose by one tablet a day each week to a maximum of 6 tablets daily as shown in table.

Morning

1st Week
2nd Week
3rd Week
4th Week

Evening

- *If* to a maximum of 6 tablets per day.
- Do not take more than 6 tablets a day.
- Children - No recommendations.

How long should you use these tablets?

How long you use these tablets depends on how well the tablets suit you.

Inflammatory bowel disease

- Ulcerative Colitis and Crohn’s Disease

- Adults and the Elderly

- Severe Flare-Ups - 2-4 tablets four times a day, with other medicines such as corticosteroids and following morning dose. Mild/Moderate Flare-Ups - 2-4 tablets four times a day, but not always with other medicines.

Children 2 years of age and over - Your doctor will tell you what dose your child will need to use. This will be based on your child’s weight.

Rheumatoid arthritis

- Adults and the Elderly - Start on one tablet each day for the first week. Then, increase the dose by one tablet a day each week to a maximum of 6 tablets daily as shown in table.

Morning

1st Week
2nd Week
3rd Week
4th Week

Evening

- *If* to a maximum of 6 tablets per day.
- Do not take more than 6 tablets a day.
- Children - No recommendations.

How long should you use these tablets?

How long you use these tablets depends on how well the tablets suit you.

Inflammatory bowel disease

- Ulcerative Colitis and Crohn’s Disease

- Adults and the Elderly

- Severe Flare-Ups - 2-4 tablets four times a day, with other medicines such as corticosteroids and following morning dose. Mild/Moderate Flare-Ups - 2-4 tablets four times a day, but not always with other medicines.

Children 2 years of age and over - Your doctor will tell you what dose your child will need to use. This will be based on your child’s weight.

Rheumatoid arthritis

- Adults and the Elderly - Start on one tablet each day for the first week. Then, increase the dose by one tablet a day each week to a maximum of 6 tablets daily as shown in table.

Morning

1st Week
2nd Week
3rd Week
4th Week

Evening

- *If* to a maximum of 6 tablets per day.
- Do not take more than 6 tablets a day.
- Children - No recommendations.
Other side-effects that may occur are:

- Indigestion, heartburn
- Feeling sick (nausea)

Common side-effects which may affect more than 1 person in 100 are listed below:

- Dizziness
- Difficulty sleeping
- Headache
- Changes in taste
- Abdominal pains
- Diarrhoea
- Being sick
- Ringing in the ears
- Blood shot eyes
- Inflamed mouth (stomatitis)
- Cough
- Itching of the skin
- Joint pain
- Proton in urine
- Fever

Uncommon side-effects which may affect more than 1 person in 1000 are listed below:

- Depression
- Fits, jerky, uncontrolled movements
- Loss of balance
- Shortness of breath
- Hair loss
- Hives
- Puffiness around the eyes and face

Since introduction to the market the following side-effects have been reported:

- Inflammation of the lining of the brain
- Severe diarrhoea
- Other blood disorders including anaemia, enlarged glands (lymph nodes)
- Blood vessel inflammation
- Loss of appetite
- Hallucinations
- Changes in mental state
- Changes in smell
- Inflammation of the sac surrounding the heart (pericarditis)
- Inflammation of the heart muscle (myocarditis)
- Blush tint to skin due to poor circulation
- Lung complications with breathlessness
- Inflammation of the salivary glands on either side of the face
- Kidney inflammation and kidney pain,
- Liver disease (hepatitis)
- Yellowing of the skin or whites of the eyes (jaundice)
- Inflammation of pancreas, which causes severe pain in the abdomen and face
- Rash, reddening or blistering of the skin, eczema,
- Tingling, numbness, pain in hands and feet
- Blood in urine
- Urine or motions may become a yellow/orange colour which is normal and harmless.
- Temporary infertility in men. Fertility returns when treatment is stopped.

Very rarely sulfasalazine has caused permanent staining of extended wear soft contact lenses. (See section 6 General Advice for further information).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. For reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE SULFASALAZINE TABLETS

Check the "expiry" date, which is printed on the carton label and bottle label. If it is out of date do not use it and contact your pharmacist.

If your tablets become discoloured or shown any other signs of deterioration, please contact your doctor before taking your medicine.

6. FURTHER INFORMATION

What Sulfasalazine tablets contain

Each gastro-resistant tablet contains 500mg sulfasalazine as the active ingredient.

Other ingredients: maize starch pregelatinised, magnesium stearate, colloidal anhydrous silicon dioxide, cellulose acetate phthalate, propylene glycol, white bees wax, camuamba wax, glyceryl monostearate self-emulsifying, macrogol 20000 and talc.

What Sulfasalazine tablets looks like and contents of the pack

Sulfasalazine tablets are yellow film-coated, oval gastro-resistant tablets embossed "KP" on one side and "1GZ" on the other.

They are coated with a film, which stops them breaking up until they leave the stomach. The tablets are the colour of the medicine itself. They contain no artificial colouring.

Sulfasalazine tablets comes in bottle containing 100 tablets.

General Advice

Because the tablets are coloured yellow they may cause your urine or motions to become a yellow/orange colour. This is normal and harmless but can stain fabric. Any Sulfasalazine tablets soiled fabric should be put in to soak. Difficult stains may be removed with a solution of washing soda. Always test the effect of soda on a small piece of the fabric first. Then apply a mild acid such as white vinegar.

Sulfasalazine has caused permanent staining of extended wear soft contact lenses. Although this happened very rarely. Daily-wear soft contact lenses and gas permeable lenses respond to standard cleaning if this happens.

Where can I get more advice about Ulcerative Colitis and Crohn's Disease?
The National Association for Colitis and Crohn's Disease (NACC) has local groups which offer meetings, events and information for patients. They may be contacted at NACC, P.O. Box 205, St. Albans, Herts, AL1 1AB.

Leaflet revision and issue date (Ref) 13.06.14[5]