

<p>Leaflet outside (Prima) 101 mm Page 32</p> <p>10 mm Glue</p> <p>Each tablet contains sulfasalazine 500 mg. Use as directed by a doctor. Oral use. Store below 25° C. Read the leaflet before use. Keep out of the sight and reach of children. MA Holder: Pfizer Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, UK. PL 00057/1044</p> <p>Salazopyrin® Tablets 500 mg</p> <p>Sulfasalazine POM</p> <p>112 Tablets</p> <p>2180883_subin</p> <p>5 013457 027020</p> <p>Peel back for package leaflet</p> <p>31</p>	<p>Leaflet outside (Prima) 111 mm Front page outside</p> <p>6 mm 16 mm Tab</p> <p>31</p>	<p>Leaflet inside (Sekunda) 111 mm Page 28</p> <p>27</p>	<p>Leaflet inside (Sekunda) 111 mm Page 5</p> <p>4</p>	<p>Leaflet outside (Prima) 111 mm Page 24</p> <p>23</p>	<p>Leaflet outside (Prima) 111 mm Page 9</p> <p>Unless your doctor has told you otherwise, the usual doses for the following conditions are: Ulcerative Colitis Adults and the Elderly • Severe Flare-Ups 2-4 tablets four times a day, with other medicines such as steroids. Do not leave more than 8 hours between the evening and following morning dose. • Mild/Moderate Flare-Up 2-4 tablets four times a day, but not always with other medicines. • Maintenance dose to control your flare ups Once the flare-up is controlled the dose is slowly reduced to 4 tablets each day. Your doctor will tell you how to reduce your dose. This lower dose may be continued for some time to help stop other flare-ups.</p> <p>8</p>	<p>Leaflet inside (Sekunda) 111 mm Page 20</p> <p>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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine. 5. How to store Salazopyrin Tablets 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 bottle after EXP. The expiry date refers to the last day of that month. Store your tablets below 25° C in a dry place. 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.</p> <p>19</p>	<p>Leaflet inside (Sekunda) 111 mm Page 13</p> <p>4. Possible side effects Like all medicines, this medicine can cause side effects, although not everybody gets them. Stop taking Salazopyrin Tablets and tell your doctor immediately if you experience any of the following symptoms after taking this medicine. Although they are very rare, these symptoms can be serious. • An allergic reaction such as sudden wheeziness, difficulty in breathing, swelling of the mouth and tongue. These may be signs of a condition known as Stevens Johnson Syndrome (SJS), or toxic epidermal necrolysis (TEN). Your doctor will stop your treatment in these cases.</p> <p>12</p>	<p>24 mm 111 mm 6 mm 16 mm Tab</p> <p>Each tablet contains sulfasalazine 500 mg. Use as directed by a doctor. Oral use. Store below 25° C. Read the leaflet before use. Keep out of the sight and reach of children. MA Holder: Pfizer Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, UK. PL 00057/1044</p> <p>Salazopyrin® Tablets 500 mg</p> <p>Sulfasalazine POM</p> <p>112 Tablets</p> <p>2180883_subin</p> <p>5 013457 027020</p> <p>Peel back for package leaflet</p> <p>For proofreading of Braille</p> <p>24 mm 111 mm 6 mm 16 mm Tab</p>
<p>16 mm 6 mm Tab/Glue</p> <p>Leaflet inside (Sekunda) 111 mm Page 2 (Front page inside)</p> <p>Package leaflet: Information for the patient</p> <p>Salazopyrin® Tablets 500 mg sulfasalazine</p> <p>Read all of this leaflet carefully before you take this medicine because it contains important information for you.</p> <ul style="list-style-type: none"> 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours. <p>1</p>	<p>Leaflet inside (Sekunda) 111 mm Page 31</p> <p>30</p>	<p>Leaflet outside (Prima) 111 mm Page 6</p> <p>5</p>	<p>Leaflet outside (Prima) 111 mm Page 27</p> <p>26</p>	<p>Leaflet inside (Sekunda) 111 mm Page 10</p> <p>9</p>	<p>Leaflet inside (Sekunda) 111 mm Page 23</p> <p>22</p>	<p>Leaflet outside (Prima) 111 mm Page 14</p> <ul style="list-style-type: none"> If you have a serious skin condition with a rash (sometimes confined to the cheeks and bridge of the nose) involving your skin or blistering. It may be triggered or aggravated by sunlight. Should this occur, stop taking this medicine, avoid strong sunlight and contact your doctor promptly. If you are generally feeling unwell, have a fever, have pain in your joints, swollen glands, rash and itching. These may be signs of a condition known as serum sickness. Your doctor will stop your treatment in these cases. <p>Tell your doctor immediately if you experience any of the following symptoms after taking this medicine as they will stop treatment in these cases:</p> <ul style="list-style-type: none"> If you notice any unexplained bleeding. If you notice bruising, fever, rash, pain (paleness), a severe sore throat or tiredness. These may be the first signs of an abnormality of the blood, including decreases in the number of red cells, white cells or platelets. Your doctor may take regular blood samples to test for these effects. <p>13</p>	<p>Leaflet outside (Prima) 111 mm Page 19</p> <ul style="list-style-type: none"> 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 (See section 6) Temporary infertility in men. Fertility returns when treatment is stopped. Normal contraception should still be used Deficiency in folic acid (may cause fatigue). <p>Very rarely sulfasalazine has caused permanent staining of extended wear soft contact lenses (See section 6).</p> <p>18</p>	<p>24 mm 111 mm 6 mm 16 mm Tab</p> <p>Base label (Selfadhesive)</p> <p>24 mm 10 mm 96 mm 8 mm 19 mm Tab/Glue</p> <p>Each tablet contains sulfasalazine 500 mg. Use as directed by a doctor. Oral use. Store below 25° C. Read the leaflet before use. Keep out of the sight and reach of children. MA Holder: Pfizer Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, UK. PL 00057/1044</p> <p>Salazopyrin® Tablets 500 mg</p> <p>Sulfasalazine POM</p> <p>112 Tablets</p> <p>2180883_subin</p>
<p>Leaflet outside (Prima) 111 mm Page 30</p> <p>29</p>	<p>Leaflet outside (Prima) 111 mm Page 3</p> <p>2</p>	<p>Leaflet inside (Sekunda) 111 mm Page 26</p> <p>25</p>	<p>Leaflet inside (Sekunda) 111 mm Page 7</p> <p>6</p>	<p>Leaflet outside (Prima) 111 mm Page 22</p> <p>21</p>	<p>Leaflet outside (Prima) 111 mm Page 11</p> <p>10</p>	<p>Leaflet inside (Sekunda) 111 mm Page 18</p> <ul style="list-style-type: none"> Other blood disorders including anaemia, enlarged glands (lymph nodes), glandular fever, persistent sore throat 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) Bluish tint or paleness 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, kidney stones Liver disease (hepatitis) <p>17</p>	<p>Leaflet inside (Sekunda) 111 mm Page 15</p> <p>Tests on your blood, kidneys, liver and urine Your doctor will be taking blood tests to check your blood, your kidneys before you start treatment and regularly during treatment. They will also measure substances produced by your liver known as enzymes (liver function tests) at regular intervals. They may also test your urine for protein and blood.</p> <p>Other side effects that may occur are:</p> <ul style="list-style-type: none"> Indigestion, heartburn Feeling sick (nausea) Difficulty sleeping Headache <p>Common: may affect up to 1 in 10 people</p> <p>14</p>	<p>24 mm 10 mm 96 mm 8 mm 19 mm Tab/Glue</p> <p>Each tablet contains sulfasalazine 500 mg. Use as directed by a doctor. Oral use. Store below 25° C. Read the leaflet before use. Keep out of the sight and reach of children. MA Holder: Pfizer Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, UK. PL 00057/1044</p> <p>Salazopyrin® Tablets 500 mg</p> <p>Sulfasalazine POM</p> <p>112 Tablets</p> <p>2180883_subin</p>
<p>Leaflet inside (Sekunda) 111 mm Page 4</p> <p>Your doctor may give you Salazopyrin Tablets to treat and manage 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). The lining of the bowel becomes inflamed (red and swollen) and symptoms include abdominal pain and diarrhoea (which may contain blood and mucus). Salazopyrin 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 may affect 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.</p> <p>3</p>	<p>Leaflet inside (Sekunda) 111 mm Page 29</p> <p>28</p>	<p>Leaflet outside (Prima) 111 mm Page 8</p> <p>7</p>	<p>Leaflet outside (Prima) 111 mm Page 25</p> <p>24</p>	<p>Leaflet inside (Sekunda) 111 mm Page 12</p> <p>11</p>	<p>Leaflet inside (Sekunda) 111 mm Page 21</p> <p>20</p>	<p>Leaflet outside (Prima) 111 mm Page 16</p> <ul style="list-style-type: none"> Changes in taste Abdominal pains Diarrhoea Being sick Ringing in the ears Blood shot eyes Inflamed mouth (stomatitis) Cough Itching of the skin Purple discolouration/s on the skin Joint pain Protein in urine Fever <p>15</p>	<p>Leaflet outside (Prima) 111 mm Page 17</p> <p>Uncommon: may affect up to 1 in 100 people</p> <ul style="list-style-type: none"> Depression Fits, jerky, uncontrolled movements Ringing in the ears Shortness of breath Hair loss Dizziness Puffiness around the eyes and face Yellowing of the skin or whites of the eyes (jaundice) <p>Not known: frequency cannot be estimated from the available data</p> <ul style="list-style-type: none"> Inflammation of the lining of the brain Severe diarrhoea <p>16</p>	<p>24 mm 10 mm 96 mm 8 mm 19 mm Tab/Glue</p>

