

This information was up to date at the time of release to the Heads of Midwifery.

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Updating arrangements for the formulary should be decided upon and implemented at a local level.

Ferrous fumarate syrup (generic, Fersamal® and Galfer®)	
Legal status (GSL, P or POM on exemption list, or PGD)	<ul style="list-style-type: none"> ▪ P - midwife may supply
Patient group	Pregnant and postpartum women.
Clinical indication	<p>Antenatal:</p> <ul style="list-style-type: none"> ▪ suspected moderate iron deficiency anaemia (serum haemoglobin 85-105g/L) <p>Postnatal:</p> <ul style="list-style-type: none"> ▪ treatment of iron deficiency anaemia which was determined by serum haemoglobin (Hb) results on postnatal day 2. See local guideline for treatment threshold
Pharmacology (Onset and duration of action where appropriate)	<p>Ferrous fumarate is a soluble salt of iron which an essential component of the body.</p> <p>Iron is required for the production of haemoglobin. It is used in the treatment and prophylaxis of anaemia in accordance with local guidelines.</p> <p>In solution ferrous ions are absorbed in the proximal portion of the duodenum.</p> <p>Haemoglobin should increase by 1-2g/litre per day or 20g/litre over 3-4 weeks.</p>
Pharmaceutical form, strength, route of administration	<p>Oral syrup of ferrous fumarate 140mg/5ml. (45mg elemental iron/5ml) generic, Fersamal® or Galfer® .</p> <p>Excipients differ between preparations. Fersamal® contains sucrose.</p> <p>For oral administration.</p>
Dose, frequency and maximum number of doses or period of time for administration or supply	<p>10ml twice a day.</p> <p>Antenatal:</p> <ul style="list-style-type: none"> ▪ initially supply 1 bottle but then, if iron deficiency anaemia is confirmed, for duration of pregnancy or 3 months after haemoglobin has normalised, whichever is sooner <p>Postnatal:</p> <ul style="list-style-type: none"> ▪ while an inpatient or outpatient until discharged from midwifery care or 3 months after haemoglobin has normalised, whichever is sooner <p>Maximum duration 6 months.</p>

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<p>Contra-indications/exclusion criteria</p>	<ul style="list-style-type: none"> ▪ known hypersensitivity to any component of the medicine ▪ Know hereditary fructose intolerance (Galfer®) ▪ women with haemochromatosis, haemosiderosis, haemolytic anaemia, paroxysmal nocturnal haemoglobinuria ▪ women with active peptic ulcer, inflammatory bowel disease, regional enteritis and ulcerative colitis, intestinal strictures and diverticulae ▪ frequent blood transfusion and concomitant parenteral iron ▪ for fersamal- hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency ▪ anaemias other than those due to iron deficiency
<p>Cautions and action that will be taken if a caution applies</p>	<ul style="list-style-type: none"> ▪ before starting treatment, exclude any other cause of anaemia ▪ reduced absorption in patients who have had gastrectomy ▪ women who have treated or controlled peptic ulceration ▪ microcytic anaemia resistant to iron therapy with iron should be screened for vitamin B12 or folate deficiency ▪ women with diabetes mellitus, as this contains sugar ▪ long term use can cause dental caries - encourage good oral hygiene ▪ check for and document any allergies ▪ check and document past medical and drug history and current medication to ascertain potential for overdose ▪ if a caution applies consult with a doctor ▪ document consultation in maternity record
<p>Medicine interactions and action that will be taken if a patient is taking a medicine that may interact</p>	<ul style="list-style-type: none"> ▪ antacids, calcium and zinc preparations and cholestyramine can reduce absorption of iron. Iron reduces absorption of ciprofloxacin and other quinolones, tetracycline, levothyroxine, mycophenolate, penicillamine and zinc preparations. The antihypertensive effect of methyl dopa may be reduced ▪ absorption reduced by certain foods-see information to be given to women ▪ if there is a clinically significant drug interaction, consult with a doctor before administration or supply ▪ document consultation in maternity record ▪ refer to current BNF for latest information on interactions
<p>Potential adverse reactions and side effects including actions to be taken if adverse drug reaction is suspected</p>	<ul style="list-style-type: none"> ▪ <i>includes nausea and epigastric pain which are dose related. Black stools and constipation are common, diarrhoea can occur occasionally</i> ▪ <i>black discoloration of the teeth</i> ▪ <i>allergic reactions (due to metabisulphite in the syrup vehicle in Fersamal®)</i> ▪ <i>on labour Nil</i> ▪ <i>on the neonate Nil</i> ▪ <i>on breast feeding Nil</i> ▪ <i>if a serious adverse reaction is suspected please report to the MHRA Yellow Card Scheme. http://yellowcard.mhra.gov.uk/</i>

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Overdose	<ul style="list-style-type: none"> ▪ ingestion of 20 mg/kg elemental iron is potentially toxic and 200-250 mg/kg is potentially fatal ▪ symptoms of nausea, abdominal pain, vomiting and diarrhoea occur within 60 minutes of ingestion. Vomit and stools may be coloured grey or black. There may be evidence of hypoperfusion (cool peripheries and hypotension), metabolic acidosis and systemic toxicity. In serious cases there can be a recurrence of vomiting and gastrointestinal bleeding 12 hours after ingestion. Shock can result from hypovolaemia or direct cardiotoxicity. Evidence of hepatocellular necrosis appears at this stage with jaundice, bleeding, hypoglycaemia, encephalopathy and positive ion gap metabolic acidosis. Poor tissue perfusion may lead to renal failure. Rarely, gastric scarring causing stricture or pyloric stenosis (alone or in combination) may lead to partial or complete bowel obstruction 2-5 weeks after ingestion ▪ cardiovascular collapse and coma may follow - woman may recover or further deteriorate with pulmonary oedema, convulsions, anuria, hyperthermia, severe shock, metabolic acidosis, coagulation abnormalities, hypoglycaemia or hyperglycaemia ▪ immediate assessment/treatment is essential - refer to medical staff ▪ manage in accordance with established treatment guidelines or see BNF overdose section ▪ for further advice contact National Poisons Centre 0344 892 0111
Action if patient declines	<ul style="list-style-type: none"> ▪ refer to authorised prescriber or doctor ▪ document in maternity record
Additional advice and information	<ul style="list-style-type: none"> ▪ advise women to avoid the following for one to two hours before and after taking this medicine: tea, coffee, milk, eggs and whole grains, as they reduce the absorption of iron ▪ medicine which interacts with iron should not be taken within one to two hours of iron ▪ Women taking levothyroxine should separate levothyroxine and iron doses by 4 hours ▪ iron is better absorbed on an empty stomach and should be taken one to two hours before meals, but if gastro-intestinal side effects are intolerable, advise women to take just after food ▪ give dietary advice to women to optimise their iron intake ▪ encourage women to drink plenty of fluids and increase the fibre in their diet to prevent the development of constipation ▪ recommend taking with a glass of orange juice to increase absorption ▪ advise to contact midwife/GP if condition worsens or symptoms persist
Patient monitoring arrangements during and after treatment and follow-up required	<p>Monitor both antenatal and post natal women in accordance with local guidelines.</p>
Particular storage requirements	<p>-</p>

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References

1. Summary of Product Characteristics
<http://www.medicines.org.uk> Fersamal® Text revision 18.9.2019 and Galfer® text revision 19.2.2019. Accessed 16.12.2019
3. <http://www.bnf.org>