PrescQIPP Community Interest Company

Omeprazole suspension and oral solution (SPOT-List)

Omeprazole oral suspension appears in the top ten Specials Prescribing Optimisation Tool list (SPOT-List). In England and Wales there is a total annual spend of over £3.8 million for unlicensed omeprazole specials.

Omeprazole is often prescribed for gastro-oesophageal reflux disease (GORD).[1] Gastro-oesophageal reflux disease (GORD) describes the reflux of gastric contents into the oesophagus, causing symptoms such as heartburn and acid regurgitation.[2] Omeprazole reduces the amount of acid in the stomach, which reduces the symptoms of GORD and helps protect the oesophagus.[1]

Recommendations

- Ensure non-pharmacological methods have been tried to manage symptoms.
- Where possible, an alginate first line, then histamine 2 receptor antagonist (H2RA), for example ranitidine should be tried. Before initiating a proton pump inhibitor (PPI), consider the long term risks of treatment. See PrescQIPP bulletin B92: Safety of long term PPIs for further information https://www.prescqipp.info/safety-of-long-term-ppis/viewcategory/336
- If a PPI is required, consider the one with lowest acquisition cost.
- Omeprazole oral suspension is an unlicensed special. Review prescribing and switch to capsules or dispersible tablets if clinically appropriate.
- If a soluble tablet is required, lansoprazole orodispersible tablets are less costly than omeprazole dispersible tablets.
- Review adults for continued clinical need.
- In infants/children, review continued need once child starts weaning.
- In cases where there has been long term prescribing, consider stepping down and then stopping. See PrescQIPP Bulletin 92: Safety of long term proton pump inhibitors (PPIs) for more information available at https://www.prescqipp.info/safety-of-long-term-ppis/viewcategory/336
- If an infant/child requires a liquid formulation, and the dose can be rounded up to 10mg, capsules or dispersible tablets can be given as they can be mixed or dispersed in liquid. It is essential to ensure that the patient's parent/carer is competent and compliant to do this.
- Adults with swallowing difficulties and children who can drink or swallow semi-solid food can be given omeprazole capsules or dispersible tablets instead of the unlicensed liquid formulation.
- If a patient requires the PPI via a nasogastric tube, consider switching preparation to a brand of lansoprazole capsules, licensed for use via an NG tube, or Losec® capsules can be dissolved in 8.4% sodium bicarbonate to give a solution (unlicensed use). (See detail in the main text of this bulletin for further information).

Evidence

Use in the paediatric population

NICE have published guidance on the management of gastro-oesophageal reflux disease: diagnosis and management in children and young people NG1.[2] NICE Clinical Knowledge Summaries (CKS) have summarised the guidance as follows:[3]

- Breast fed infants with frequent regurgitation: consider a 1 - 2 week trial of alginate therapy (for example Gaviscon® Infant) mixed with water and given after each feed.
- Formula fed infants need a stepped approach. Review the infants total feed volume, consider use of feed thickeners and then consider a 1 - 2 week trial of alginate therapy (Gaviscon® Infant) added to formula.
- For infants that are both breastfed and formula fed; if symptoms improve after a 1 - 2 week trial of alginate therapy (e.g. Gaviscon® Infant) continue with this therapy. Then stop treatment at regular intervals (for example every two weeks) in order to see if symptoms have improved and if it is possible to stop treatment completely.
- If symptoms remain troublesome despite a 1 - 2 week trial of alginate therapy, it may be appropriate to consider prescribing a four week trial of a proton pump inhibitor (such as oral omeprazole) or a histamine-2 receptor antagonist (such as oral ranitidine).
- If symptoms do not stabilise with the combination of an alginate and managing feed regimens, the patient may be referred to specialist services and a short course of omeprazole suspension might be recommended. It is important to note that omeprazole suspension (unlicensed) is the only PPI liquid preparation available for administration to infants.

The BNF for Children lists conditions for which omeprazole can be used[4] and gives the following doses for gastro-oesophageal reflux disease, acid-related dyspepsia; treatment of duodenal and benign gastric ulcers including those complicating NSAID therapy; Zollinger-Ellison syndrome; fat malabsorption despite pancreatic enzyme replacement therapy in cystic fibrosis.

Dosages: By mouth[4]
Neonate 700 micrograms/kg once daily, increased if necessary after 7 - 14 days to 1.4mg/kg; some neonates may require up to 2.8mg/kg once daily
Child 1 month - 2 years 700 micrograms/kg once daily, increased if necessary to 3mg/kg (max. 20mg) once daily
Child body-weight 10 - 20kg 10mg once daily increased if necessary to 20mg once daily (in severe ulcerating reflux oesophagitis, max. 12 weeks at higher dose)
Child body-weight over 20kg 20mg once daily increased if necessary to 40mg once daily (in severe ulcerating reflux oesophagitis, max. 12 weeks at higher dose)

Omeprazole oral suspension but not oral solution appears as an unlicensed special in the Drug Tariff.[5] Although it is more expensive than using dispersible tablets, it might be necessary to use oral suspension to provide the correct dose for children and infants. As omeprazole oral solution is not listed in the Drug Tariff, it does not have a fixed cost and therefore prices charged can vary.

Whenever possible, if doses can be rounded up to the nearest 10mg, omeprazole capsules or dispersible tablets should be prescribed and administered via an oral syringe. See below for further instructions.

Use in the adult population

Please refer to NICE Clinical Guidance CG184; 'Dyspepsia and gastro-oesophageal reflux disease: Investigation and management of dyspepsia, symptoms suggestive of gastro-oesophageal reflux disease', September 20146 for information on how to manage the adult population.

The PrescQIPP bulletin (92), Safety of long-term proton pump inhibitors (PPIs) https://www.prescqipp.info/safety-of-long-term-ppis/viewcategory/336 can be used to support discussion with clinicians when looking at the evidence base and need for PPI prescribing.

NICE CG184 advises:[6]

First line treatment and lifestyle recommendations:

- Offer simple advice regarding lifestyle factors that may affect reflux (such as avoiding eating just before going to bed and losing weight, if applicable).
- Offer a full-dose proton pump inhibitor for 4 - 8 weeks.
- If symptoms recur after initial treatment, offer a PPI at the lowest dose possible to control symptoms
- Offer people who need long term management of dyspepsia symptoms an annual review of their condition, and encourage them to try stepping down or stopping treatment (unless there is an underlying condition or co-medication that needs continuing treatment).

Adults with swallowing difficulties should be reviewed for continued need for omeprazole suspension. They should be considered for switching to omeprazole capsules or dispersible tablets.

Adults with swallowing difficulties and children who can drink or swallow semi-solid food can open omeprazole capsules and swallow the contents with half a glass of water or after mixing the contents in a slightly acidic fluid, e.g. fruit juice or applesauce, or in non-carbonated water. They should be advised that the dispersion should be taken immediately (or within 30 minutes) and always be stirred just before drinking and rinsed down with half a glass of water.[7]

Alternatively they can suck the capsule and swallow the pellets with half a glass of water. The enteric-coated pellets must not be chewed.

Omeprazole tablets can be broken and dispersed in a spoonful of non-carbonated water and if wished, mixed with some fruit juices or applesauce. The dispersion should be taken immediately (or within 15 minutes) and always be stirred just before drinking and rinsed down with half a glass of water. DO NOT USE milk or carbonated water. The enteric-coated pellets must not be chewed.[8]

Adults and children with nasogastric feeding tubes

The Handbook of Drug Administration via Enteral Feeding Tubes suggests the following when administering omeprazole via an NG tube:

Losec capsules

Extemporaneous Preparation: 20mg capsule content can be dissolved in 10ml of 8.4% sodium bicarbonate to give a 2mg/ml solution. This is stable for 14 days at room temperature and for 45 days when refrigerated. This solution can be administered via a nasogastric duodenal or jejuna tube without risk of blockage or reduced efficacy.[9]

Information is available regarding other brands, but in most cases the manufacturer will need to be contacted. Please note this is an unlicensed use of omeprazole.

Alternatively, a brand of lansoprazole licenced for administration via a NG tube can be prescribed (see SPC for more details):

Actavis:[10,11] Capsules may be opened and granules mixed with 40ml of apple juice for administration through a nasogastric tube After preparing the suspension or mixture, the drug should be administered immediately.

Consilient Health[12] and Zentiva[13]: Unsuitable for use with an NG tube

Orodispersible tablets (Lupin and Zoton FasTab):[14,15] Can be dispersed in a small amount of water and administered via a naso-gastric tube or oral syringe (see SPCs for full instructions - these details are correct at time of writing but might be subject to change. Readers are advised to check the SPCs for current information.)

Costs and savings available

Cost of Drug Tariff specials[5]

Preparation	Minimum volume (ml)	Price for minimum volume (£)	Price per ml thereafter (p)
Omeprazole 5mg/5ml oral suspension	70	£91.00	1p
Omeprazole 10mg/5ml oral suspension	75	£87.12	2p
Omeprazole 20mg/5ml oral suspension	150	£108.35	2p
Omeprazole 40mg/5ml oral suspension	100	£137.47	3p

Cost of licensed preparations of omeprazole and lansoprazole[5]

Preparation	Quantity	Cost (£)
Omeprazole 10mg - 40mg gastro-resistant capsules	28	£1.02 to £3.44
Omeprazole 10mg - 40mg dispersible gastro-resistant tablets	28	£7.75 to £23.20
Omeprazole 10mg - 40mg gastro-resistant tablets	28	£7.90 to £24.36
Lansoprazole 15mg - 30mg gastro-resistant capsules	28	£1.03 to £1.29
Lansoprazole 15mg - 30mg orodispersible tablets	28	£2.62 to £4.65

Over £3.8 million is spent annually on unlicensed omeprazole liquid preparations in England and Wales (ePACT September to November 2015). Reviewing appropriateness of PPI therapy and stopping treatment where applicable or switching to a licenced alternative can lead to significant savings and improved safety. **A 50% reduction in prescribing could save over £1.9 million annually across England and Wales. This equates to £3,210 per 100,000 patients.**

Savings will be offset by the price of licenced product switched to if a switch is appropriate- however as these will be chosen on an individual patient basis, it is difficult to calculate more precise savings.

Summary

- Review prescribing of omeprazole liquid specials (both suspension and oral solution). For individual patients consider whether there is a continued need for prescribing and if so whether an alternative licenced preparation can be prescribed for the patient instead of a special.
- Review prescribing regularly to assess for continued need.

References

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Additional PrescQIPP resources

Data pack

Available here: https://www.prescqipp.info/resources/viewcategory/459-omeprazole-spot-list

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Non-subscriber publication July 2016.

At the time of publication the PrescQIPP NHS Programme was hosted by Papworth NHS Trust and the Eastern Academic Health Science Network.

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