SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Aspirin 75mg Dispersible Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 75mg acetylsalicylic acid.

Excipients with known effect
Each Aspirin dispersible tablet contains:
34.25mg of Lactose
0.75mg Saccharin sodium (0.084mg sodium)

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Dispersible tablet.
White, circular, flat, bevelled-edge, uncoated tablets impressed “C” and the identifying letters “AY” on one face.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the secondary prevention of thrombotic cerebrovascular or cardiovascular disease, following by-pass surgery and in patients suffering from unstable angina.

4.2 Posology and method of administration

Posology
The tablets should be dispersed in water before administration.

The advice of a doctor should be sought before commencing therapy for the first time.

The usual dosage for long term use is 1-2 tablets (75-150mg) once daily. In some circumstances a higher dose may be appropriate, especially in the short-term, and up to 4 tablets (300mg) a day may be used on the advice of a doctor. The usual adult dose is recommended in the absence of severe renal or hepatic insufficiency (see sections 4.3 and 4.4). Treatment should be reviewed at regular intervals.

Paediatric population
Do not give to children aged under 16 years, unless specifically indicated (e.g. for Kawasaki's disease) (see section 4.4).

Method of Administration
To be dispersed in water for oral administration.

4.3 Contraindications

Aspirin should not be taken by patients with the following conditions:

- Known hypersensitivity to the active substances or to any of the excipients listed in section 6.1, other salicylates or non-steroidal anti-inflammatory drugs (a patient may have developed anaphylaxis, angioedema, asthma and may suffer an attack or faint, certain patients may suffer from bronchospasm, rhinitis or urticaria induced by aspirin or other NSAIDs)
- Nasal polyps associated with asthma (high risk of severe sensitivity reactions)
- Active, or history of recurrent peptic ulcer, dyspepsia and/or gastric/intestinal haemorrhage, or other kinds of bleeding such as cerebrovascular haemorrhages;
- Haemorrhagic diathesis; coagulation disorders such as haemophilia and thrombocytopenia;
- Concurrent anticoagulant therapy should be avoided
- Severe hepatic impairment
- Severe renal impairment
- Severe cardiac failure
- Doses >100 mg/day during the third trimester of pregnancy (see section 4.6);
- Cancer or rheumatoid arthritis where Methotrexate is used at doses >15mg/week (see section 4.5)
- Gout (treated by probenecid)
- children under 16 years old, unless specifically indicated (e.g. Kawasaki's disease).

4.4 Special warnings and precautions for use

Aspirin is not suitable for use as an anti-inflammatory/analgesic/antipyretic.

Before commencing long-term aspirin therapy for the management of cardiovascular or cerebrovascular disease, patients should consult their doctor who can advise on the relative benefits versus the risks for the individual patient.

Paediatric population

There is a possible association between aspirin and Reye's syndrome when given to children. Reye's syndrome is a very rare disease, which affects the brain and liver, and can be fatal. For this reason aspirin should not be given to children aged under 16 years unless specifically indicated (e.g. for Kawasaki's disease).

There is an increased risk of haemorrhage particularly during or after operative procedures (even in cases of minor procedures, e.g. tooth extraction). Use with caution before surgery, including tooth extraction. Temporary discontinuation of treatment may be necessary.

Aspirin is not recommended during menorrhagia where it may increase menstrual bleeding.

Aspirin is to be used with caution in cases of hypertension and when patients have a past history of gastric or duodenal ulcer or haemorrhagic episodes or are undergoing therapy with anticoagulants.

Patients should report any unusual bleeding symptoms to their physician. If gastrointestinal bleeding or ulceration occurs the treatment should be withdrawn.

Aspirin should be used with caution in patients with moderately impaired renal or hepatic function (contraindicated if severe), or in patients who are dehydrated since the use of NSAIDs may result in deterioration of renal function. Liver function tests should be performed regularly in patients presenting slight or moderate hepatic insufficiency.

Aspirin may promote bronchospasm and asthma attacks or other hypersensitivity reactions. Risk factors are existing asthma, hay fever, nasal polyps or chronic respiratory diseases. The same applies for patients who also show allergic reaction to other substances (e.g. with skin reactions, itching or urticaria).

Serious skin reactions, including Steven-Johnsons syndrome, have rarely been reported in association with the use of acetylsalicylic acid (see section 4.8). Aspirin should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.

Elderly patients are particularly susceptible to the adverse effects of NSAIDs, including acetylsalicylic acid especially gastrointestinal bleeding and

perforation which may be fatal (see section 4.2). Where prolonged therapy is required, patients should be reviewed regularly.

Concomitant treatment with aspirin and other drugs that alter haemostasis (i.e. anticoagulants such as warfarin, thrombolytic and antiplatelet agents, anti-inflammatory drugs and selective serotonin reuptake inhibitors) is not recommended, unless strictly indicated, because they may enhance the risk of haemorrhage (see section 4.5). If the combination cannot be avoided, close observation for signs of bleeding is recommended.

Caution should be advised in patients receiving concomitant medications which could increase the risk of ulceration, such as oral corticosteroids, selective serotonin-reuptake inhibitors and deferasirox (see section 4.5).

Acetylsalicylic acid in low doses reduces uric acid excretion. Due to this fact, patients who tend to have reduced uric acid excretion may experience gout attacks (see section 4.5).

The risk of hypoglycaemic effect with sulfonylureas and insulins may be potentiated with Aspirin taken at over dosage (see section 4.5).

Aspirin should be used with caution in patients with:

- anaemia (may be exacerbated by GI blood loss)
- cardiac failure (conditions which predispose to fluid retention)
- glucose-6-phosphate dehydrogenase deficiency (aspirin rarely causes haemolytic anaemia)
- systemic lupus erythematosus and other connective tissue disorders (hepatic and renal function may be impaired in these conditions)
- thyrotoxicosis (may be exacerbated by large doses of salicylates)
- Vaccine recipients should avoid use of salicylates for 6 weeks after varicella vaccination (see section 4.5).

Medication Overuse Headache (MOH):

After long term treatment with analgesics, headache may develop or aggravate. Headache caused by overuse of analgesics (MOH - medication-overuse headache) should be suspected in patients who have frequent or daily headaches despite (or because of) regular use of analgesics. Patients with medication overuse headache should not be treated by increasing the dose. In such cases the use of analgesics should be discontinued in consultation with a doctor.

Aspirin Dispersible tablets contain lactose

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine, as it contains lactose.

Aspirin Dispersible tablets contains saccharin sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

4.5 Interaction with other medicinal products and other forms of interaction

Contraindicated combinations

- *Methotrexate (used at doses >15 mg/week):*
  The combined drugs, methotrexate and acetylsalicylic acid, enhance haematological toxicity of methotrexate due to the decreased renal clearance of methotrexate by aspirin. Therefore, the concomitant use of methotrexate (at doses >15 mg/week) with aspirin is contraindicated (see section 4.3).

Not recommended combinations

- *Uricosuric agents, e.g. probenecid*
  Salicylates reverse the effect of probenecid. The combination should be avoided.

Combinations requiring precautions for use or to be taken into account

- *Metamizole*
  Metamizole may reduce the effect of acetylsalicylic acid on platelet aggregation, when taken concomitantly. Therefore, this combination should be used with caution in patients taking low dose aspirin for cardioprotection.

- *Anticoagulants e.g. coumarin, heparin, warfarin and phenindione.*
  Increased risk of bleeding due to inhibited thrombocyte function, injury of the duodenal mucosa and displacement of oral anticoagulants from their plasma protein binding sites. The bleeding time should be monitored (see section 4.4).

- *Anti-platelet agents (e.g clopidogrel and dipyridamole) and selective serotonin reuptake inhibitors (SSRIs; such as sertraline or paroxetine)*
  Increased risk of gastrointestinal bleeding (see section 4.4).

- *Antidiabetics, e.g. sulphonylureas*
  Salicylics may increase the hypoglycaemic effect of sulphonylureas.

- *Digoxin and lithium*
  Acetylsalicylic acid impairs the renal excretion of digoxin and lithium, resulting in increased plasma concentrations. Monitoring of plasma concentrations of digoxin and lithium is recommended when initiating and terminating treatment with acetylsalicylic acid. Dose adjustment may be necessary

- *Diuretics and antihypertensives*
  NSAIDs may decrease the antihypertensive effects of diuretics and other antihypertensive agents. As for other NSAIDs concomitant administration with ACE-inhibitors increases the risk of acute renal insufficiency.

Diuretics: Risk of acute renal failure due to the decreased glomerular filtration via decreased renal prostaglandin synthesis. Hydrating the patient and monitoring renal function at the start of the treatment is recommended.

- *Carbonic anhydrase inhibitors (acetazolamide)*
  May result in severe acidosis and increased central nervous system toxicity

- *Systemic corticosteroids*
  The risk of gastrointestinal ulceration and bleeding may be increased when acetylsalicylic acid and corticosteroids are co-administered (see section 4.4).

- *Methotrexate (used at doses <15 mg/week):*
  The combined drugs, methotrexate and acetylsalicylic acid, may increase haematological toxicity of methotrexate due to decreased renal clearance of methotrexate by acetylsalicylic acid. Weekly blood count checks should be done during the first weeks of the combination. Enhanced monitoring should take place in the presence of even mildly impaired renal function, as well, as in elderly.

- *Other NSAIDs*
  Increased risk of ulcerations and gastrointestinal bleeding due to synergistic effects.

- *Ibuprofen*
  Experimental data suggest that ibuprofen may inhibit the effect of low dose acetylsalicylic acid on platelet aggregation when they are dosed concomitantly. However, the limitations of these data and the uncertainties regarding extrapolation of ex vivo data to the clinical situation imply that no firm conclusions can be made for regular ibuprofen use, and no clinically relevant effect is considered to be likely for occasional ibuprofen use (see section 5.1).

- *Ciclosporin, tacrolimus*
  Concomitant use of NSAIDs and ciclosporin or tacrolimus may increase the nephrotoxic effect of ciclosporin and tacrolimus. The renal function should be monitored in case of concomitant use of these agents and acetylsalicylic acid.

- *Valproate*
  Acetylsalicylic acid has been reported to decrease the binding of valproate to serum albumin, thereby increasing its free plasma concentrations at steady state.

- *Phenytoin*
  Salicylate diminishes the binding of phenytoin to plasma albumin. This may lead to decreased total phenytoin levels in plasma, but increased free phenytoin fraction. The unbound concentration, and thereby the therapeutic effect, does not appear to be significantly altered.

- *Alcohol*

Concomitant administration of alcohol and acetylsalicylic acid increases the risk of gastrointestinal bleeding.

The following drug interactions should be considered when prescribing aspirin:

Antacids, carbonates and absorbents - Antacids will reduce the effect of aspirin. Principal incompatibilities are iron salts, carbonates and alkali hydroxides.

- *Metoclopramide and domperidone* - increased rate of absorption of aspirin.
- *Mifepristone* - avoid aspirin until 8-12 days after mifepristone.
- *Ototoxic medicine* (*eg* vancomycin) - potential for ototoxicity increased. Hearing loss may occur and may progress to deafness even after discontinuation of the medication. Effects may be reversible but are usually permanent.
- *Laboratory investigations* - aspirin may interfere with some laboratory tests such as urine 5-hydroxyundoleacetic acid determinations and copper sulphate urine sugar tests.
- *ACE inhibitors* – reduced hypotensive effect, increased risk of renal impairment and hypokalaemia. Monitoring of renal function may be required.
- *Calcium-channel blockers* – reduced hypotensive effects, increased antiplatelet effect which rarely results in pro-longed bleeding time.
- *Varicella vaccine* - Vaccine recipients should avoid use of salicylates for 6 weeks after vaccination with varicella vaccine as Reye's syndrome has been reported following use of salicylates during wild-type varicella infection (see section 4.4).

Ginkgo Biloba – possible increase in risk of bleeding.

4.6 Fertility, pregnancy and lactation

Pregnancy

Low doses (up to 100 mg/day):

Clinical studies indicate that doses up to 100 mg/day for restricted obstetrical use, which require specialised monitoring, appear safe.

Doses of 100- 500 mg/day:

There is insufficient clinical experience regarding the use of doses above 100 mg/day up to 500 mg/day. Therefore, the recommendations below for doses of 500 mg/day and above apply also for this dose range.

Doses of 500 mg/day and above:

Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/fetal development. Data from epidemiology studies suggest an increased risk of miscarriage and of cardiac malformation after use of a prostaglandin synthesis inhibitor in early pregnancy. The absolute risk for cardiovascular malformation was increased from less than 1%, up to approximately 1.5%. The risk is believed to increase with dose and duration of

therapy. In animals, administration of a prostaglandin synthesis inhibitor has been shown to result in increased pre- and post-implantation loss and embryo-foetal lethality. In addition, increased incidences of various malformations, including cardiovascular, fissure of the spine and skull, facial clefts and malformations of the CNS, viscera and skeleton, have been reported in animals given a prostaglandin synthesis inhibitor during the organogenetic period.
During the first and second trimester of pregnancy, acetylsalicylic acid should not be given unless clearly necessary. If acetylsalicylic acid is used by a woman attempting to conceive, or during the first and second trimester of pregnancy, the dose should be kept as low and duration of treatment as short as possible.

During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the foetus to:
- cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension);
- renal dysfunction, which may progress to renal failure with oligo-hydroamniosis;

the mother and the neonate, at the end of pregnancy, to:
- possible prolongation of bleeding time, an anti-aggregating effect which may occur even at very low doses.
- inhibition of uterine contractions resulting in delayed or prolonged labour.

Regular or high dose use of salicylates late in pregnancy may result in:
- increased risk of still birth or neonatal death
- decreased birth weight
- kernicterus in jaundiced neonates

Consequently, acetylsalicylic acid at doses of 100 mg/day and higher is contraindicated during the third trimester of pregnancy and should be avoided during the late stages of labour and during the delivery of a premature infant.

Breast-feeding
Use in children under 16 years old is contraindicated due to possible risk of Reye's syndrome. Since aspirin is distributed into breast milk, breast fed infants may also be at risk. Since adverse effects for the infant have not been reported up to now, short-term use of the recommended dose does not require suspending breastfeeding. In cases of long-term use and/or administration of higher doses, breastfeeding should be discontinued.

Fertility
Aspirin should not be given to women wishing to become pregnant, since it is thought that prostaglandin synthesis inhibitors can reduce fertility. The effect on fertility is reversible.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed with aspirin.
Based on the pharmacodynamic properties and the side effects of acetylsalicylic acid, no influence on the reactivity and the ability to drive or use machines is expected.

4.8 Undesirable effects

Side effects are grouped on the basis of System Organ Class. Within each system organ class the frequencies are defined as: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000) and not known (cannot be estimated from the available data)

System Organ Class	Adverse Reactions and Frequency
Blood and lymphatic system disorders	*Common:* Increased bleeding tendencies. *Rare:* Thrombocytopenia, granulocytosis, aplastic anaemia. *Not known:* Cases of bleeding with prolonged bleeding time such as epistaxis, gingival bleeding. Symptoms may persist for a period of 4–8 days after acetylsalicylic acid discontinuation. As a result there may be an increased risk of bleeding during surgical procedures. Existing (haematemesis, melaena) or occult gastrointestinal bleeding, which may lead to iron deficiency anaemia (more common at higher doses). haemolytic anaemia, hypoprothrombinaemia, pancytopenia, elevated transaminase levels.
Immune system disorders	*Rare:* Hypersensitivity reactions, angio-oedema, allergic oedema, anaphylactic reactions including shock.
Metabolism and digestive system disorders	*Not known:* Hyperuricemia.
Nervous system disorders	*Rare:* Intracranial haemorrhage *Not known:* Headache, vertigo.
Ear and labyrinth disorders	*Not known:* Reduced hearing ability; tinnitus.
Vascular disorders	*Rare:* Haemorrhagic vasculitis.

Respiratory, thoracic and mediastinal disorders	*Uncommon:* Rhinitis, dyspnoea. *Rare:* Bronchospasm, asthma attacks. *Not known:* Worsening of asthma
Reproductive system and mammary disorders	*Rare:* Menorrhagia
Gastrointestinal disorders	*Common:* Dyspepsia. *Rare:* Severe gastrointestinal haemorrhage, nausea, vomiting. *Not known:* Gastric or duodenal ulcers, erosions and perforation, which can occasionally be major (may develop bloody or black tarry stools, severe stomach pain and vomiting blood), diarrhoea, gastrointestinal irritation (mild stomach pain, heartburn, vomiting and nausea). Fatalities have occurred.
Hepatobiliary disorders	*Not known:* Hepatic insufficiency, hepatitis (particularly in patients with SLE or connective tissue disease).
Skin and subcutaneous tissue disorders	*Uncommon:* Urticaria. *Rare:* Steven-Johnsons syndrome, Lyells syndrome, purpura, erythema nodosum, erythema multiforme.
Renal and urinary tract disorders	*Not known:* Impaired renal function, salt and water retention.

Salicylism - mild chronic salicylate intoxication may occur after repeated administration of large doses, symptoms include dizziness, tinnitus, deafness, sweating, nausea, vomiting, headache and mental confusion, and may be controlled by reducing the dose.

Paediatric population
Aspirin may be associated with the development of Reye's Syndrome (encephalopathy and hepatic failure) in children presenting with an acute febrile illness.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Although considerable inter-individual variations are involved, it can be considered that the toxic dose is about 200 mg/kg in adults and 100 mg/kg in children. The lethal dose of acetylsalicylic acid is 25-30 grams. Plasma salicylate concentrations above 300 mg/l indicate intoxication. Plasma concentrations above 500 mg/l in adults and 300 mg/l in children generally cause severe toxicity.
Overdose may be harmful for elderly patients and particularly for small children (therapeutic overdose or frequent accidental intoxications may be fatal).

Symptoms of moderate intoxications
Tinnitus, hearing disorders, headache, vertigo, confusion and gastrointestinal symptoms (nausea, vomiting and abdominal pain), dehydration, deafness, sweating, warm extremities with bounding pulses.

Symptoms of severe intoxications
Symptoms are related to severe disruption of the acid-base balance. In the first instance hyperventilation occurs, which results in respiratory alkalosis. Respiratory acidosis ensues due to suppression of the respiratory centre. In addition, metabolic acidosis occurs as a result of the presence of salicylate. Since younger children are often not seen until they have reached a late stage of intoxication, they are usually in the stage of acidosis.
Furthermore, the following symptoms may occur: haematemesis, hyperpyrexia, hypokalaemia, thrombocytopaenia, increased INR/PTR, intravascular coagulation, renal failure, non-cardiac pulmonary oedema, hyperthermia and perspiration, resulting in dehydration: feelings of restlessness, convulsions, hallucinations and hypoglycaemia. Depression of the nervous system may lead to coma, cardiovascular collapse or respiratory arrest.

Central nervous system features including confusion, disorientation, coma and convulsions are less common in adults than in children

Treatment of overdose:
If a toxic dose has been ingested, hospital admission is required. In the event of moderate intoxication, inducing the patient to vomit should be attempted.

If this fails, consider gastric lavage in adults and children who have ingested more than 500 mg/kg body weight salicylate less than 1 hour previously. Afterwards, administer activated carbon (adsorbent) and sodium sulphate (laxative).

Activated charcoal should be given as a single dose (50 g for an adult, 1 g/kg body weight for a child up to 12 years) in adults and children who have ingested more than 250mg/kg body weight salicylate, or any amount of methyl salicylate, less than 1 hour previously.

The plasma salicylate concentration should be measured, although the severity of poisoning cannot be determined from this alone and the clinical and biochemical features must be taken into account. U & Es, INR/PTR, blood glucose, pH and electrolytes should be measured. Correct metabolic acidosis with intravenous 8.4% sodium bicarbonate (first check serum potassium). Forced diuresis should not be used since it does not enhance salicylate excretion and may cause pulmonary oedema.

Elimination is increased by urinary alkalinisation, which is achieved by the administration of 1.26% sodium bicarbonate. Alkalisation of the urine (250 mmol $NaHCO_3$, for three hours) whilst checking urine pH levels. Fluid losses replaced and forced alkaline diuresis (eg with sodium bicarbonate) should be considered when the plasma salicylate concentration is greater than 500mgl^{-1} (3.6mmol l^{-1}) in adults or 300mgl^{-1} (2.2mmol l^{-1}) in children.

Haemodialysis is the treatment of choice for severe poisoning and should be considered in patients with plasma salicylate concentrations >700 mg/L (5.1 mmol/L), or lower concentrations associated with severe clinical or metabolic features. Patients under 10 years or over 70 have increased risk of salicylate toxicity and may require dialysis at an earlier stage.
Other symptoms to be treated symptomatically.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other analgesics and antipyretics: ATC code: N02BA01

Aspirin is an anti-inflammatory analgesic and antipyretic. Aspirin inhibits platelet aggregation.

Experimental data suggest that ibuprofen may inhibit the effect of low dose aspirin on platelet aggregation when they are dosed concomitantly. In one study, when a single dose of ibuprofen
400mg was taken within 8 hours before or within 30 minutes after immediate release aspirin
(81mg), a decreased effect of aspirin on the formation of thromboxane or platelet aggregation occurred. However, the limitations of these data and the uncertainties regarding extrapolation of ex vivo data to the clinical situation imply that no firm conclusions can be made for regular ibuprofen use, and no clinically relevant effect is considered to be likely for occasional ibuprofen use.

5.2 Pharmacokinetic properties

Absorption
Absorption of non-ionised aspirin occurs in the stomach and intestine. Some aspirin is hydrolysed to salicylate in the gut wall.

Biotransformation
After absorption aspirin is rapidly converted to salicylate but during the first 20 minutes aspirin is the predominant form of the drug in the plasma.

Distribution
Aspirin is bound to plasma proteins and is widely distributed. Plasma-aspirin concentrations decline rapidly (half-life 15-20 minutes) as plasma salicylate concentrations increase. Both aspirin and salicylate have pharmacological activity; only aspirin has an anti-platelet effect.

Elimination
Salicylate is mainly eliminated by hepatic metabolism; the metabolites include salicyluric acid, salicyl phenolic glucuronide, salicylic acyl glucuronide, gentisic acid, and gentisuric acid. Salicylate is also excreted unchanged in the urine; the amount excreted by this route increases with increasing dose and also depends on urinary pH, about 30% of a dose being excreted in alkaline urine compared with 2% of a dose in acidic urine. Renal excretion involves glomerular filtration, active renal tubular secretion, and passive tubular reabsorption. Salicylates appear in breast milk and cross the placenta.

5.3 Preclinical safety data

The preclinical safety profile of acetylsalicylic acid is well documented.
In experimental animal studies, salicylates have shown no other organ injury than renal damage.
In rat studies, fetotoxicity and teratogenic effects were observed with acetylsalicylic acid at maternotoxic doses. Clinical relevance is unknown as the doses used in non-clinical studies are much higher (7 times at least) than the maximal recommended doses in targeted cardiovascular indications.
Acetylsalicylic acid was extensively investigated with regard to mutagenic and carcinogenic effects. The results as a whole show no relevant signs for any mutagenic or carcinogenic effects in mice and rat studies.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid, lactose, maize starch, saccharin sodium, calcium carbonate (E170).

6.2 Incompatibilities

Iron salts, alkalis and carbonates.

6.3 Shelf life

Shelf-life
Tablet container: 2 years
Blister pack: 1 year

Shelf-life after dilution/reconstitution
Not applicable.

Shelf-life after first opening
Not applicable.

6.4 Special precautions for storage

Store below 25°C in a dry place.
Keep container tightly closed.

6.5 Nature and contents of container

Child-resistant blister pack: (i) white 250µm PVC/30µm PE/90g/m^2 PVdC (ii) 9µm soft aluminium / 35g/m^2 glassine paper. Compliant with BS EN 14375.

PE tablet container with a child-resistant PP closure. A 2g silica gel container is included in each pack. Compliant with ISO 8317.

Pack sizes:

POM: 1000.

PP tablet container with a PE closure for dispensing purposes or supply to nursing homes. A 2g silica gel container is included in each pack.
Pack size:
POM: 1000.

Product may also be supplied in bulk packs, for reassembly purposes only, in polybags contained in tins, skillets or polybuckets filled with suitable

cushioning material. An appropriate number of 2g silica gel containers are included in each pack.
Maximum size of bulk packs: 10,000.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements for disposal.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Accord-UK Ltd
(Trading style: Accord)
Whiddon Valley
Barnstaple
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EX32 8NS

8 MARKETING AUTHORISATION NUMBER(S)

PL 0142/0377

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

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