SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Flecainide Acetate 50mg/5ml Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains 50mg flecainide acetate

Excipients with known effect

Liquid Maltitol 2.459g/5ml

Sodium 0.82mg/5ml

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral Solution

Clear, colourless to straw coloured liquid with strawberry flavour.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of AV nodal reciprocating tachycardia; arrhythmias associated with Wolff-Parkinson-White Syndrome and similar conditions with accessory pathways, when other treatment has been ineffective.

Treatment of severe symptomatic and life-threatening paroxysmal ventricular arrhythmia which has failed to respond to other forms of therapy or where other treatments have not been tolerated.

Treatment of paroxysmal atrial arrhythmias (atrial fibrillation, atrial flutter and atrial tachycardia) in patients with disabling symptoms after conversion provided that there is definite need for treatment on the basis of severity of

clinical symptoms, when other treatment has been ineffective. Structural heart disease and/or impaired left ventricular function should be excluded because of the increased risk for pro-arrhythmic effects.

4.2 Posology and method of administration

Posology

Initiation of flecainide acetate therapy and dose changes should be made under medical supervision and monitoring of ECG and plasma level. Hospitalisation could be necessary during such procedures for certain patients, especially for patients with life threatening ventricular arrhythmias. These decisions should be made under supervision of specialist.

In patients with an underlying organic cardiopathy and especially those with a history of myocardial infarction, flecainide treatment should only be started when other arrhythmic agents, other than class IC (especially amiodarone), are ineffective or not tolerated and when non-pharmacological treatment (surgery, ablation, implanted defibrillator) is not indicated. Strict medical monitoring of ECG and plasma levels during treatment is required.

Adults and adolescents (13-17 years of age):

Supraventricular arrhythmias: The recommended starting dose is 50 mg twice daily and most patients will be controlled at this dose. If required the dose may be increased to a maximum of 300 mg daily.

Ventricular arrhythmias: The recommended starting dose is 100 mg twice daily. The maximum daily dose is 400 mg and this is normally reserved for patients of large build or where rapid control of the arrhythmia is required. After 3-5 days it is recommended that the dosage be progressively adjusted to the lowest level which maintains control of the arrhythmia. It may be possible to reduce dosage during long term treatment.

Elderly patients:

In elderly patients the maximum initial daily dosage should be 100 mg daily (or 50 mg twice daily) as the rate of flecainide elimination from plasma may be reduced in elderly people. This should be taken into consideration when making dose adjustments. The dose for elderly patients should not exceed 300 mg per day (or 150 mg twice daily).

Children:

Flecainide acetate is not recommended for use in children younger than 12 years, due to a lack of data on safety and efficacy.

Plasma levels:

Based on PVC suppression, it appears that plasma levels of 200-1000ng/ml may be needed to obtain the maximum therapeutic effect. Plasma levels above 700-1000 ng/ml are associated with increased likelihood of adverse experiences especially cardiac.

Impaired renal function:

In patients with significant renal impairment (creatinine clearance of 35ml/min/1.73sq.m.or less) the maximum initial dosage should be 100mg daily (or 50mg twice daily). When used in such patients, frequent plasma level monitoring is strongly recommended. Depending on the effect and tolerability the dose may then be cautiously increased. After 6-7 days the dose may be adjusted, depending on the effect and the tolerability. Some patients with severe renal failure can have a very slow clearance of flecainide and thus a prolonged half-life (60-70 hours).

Impaired liver function:

In patients with impaired liver function, the patient should be closely monitored and the dose should not exceed 100 mg daily (or 50 mg twice daily).

Patients with a permanent pacemaker in situ should be treated with caution and the dose should not exceed 100 mg twice daily.

In patients concurrently receiving cimetidine or amiodarone close monitoring is required. In some patients the dose may have to be reduced and should not exceed 100mg twice daily. Patients should be monitored during initial and maintenance therapy.

Plasma level monitoring and ECG control are recommended at regular intervals (ECG control once a month and long term ECG every 3 months) during therapy. During initiation therapy and when the dose is increased, an ECG should be performed every 2-4 days.

When flecainide is used in patients with dosage restrictions, frequent ECG control (additional to the regular flecainide plasma monitoring) should be made. Dose adjustment should be made at intervals of 6-8 days. In such patients an ECG should be performed in weeks 2 and 3 to control the individual dosage.

Switch over from IV to oral therapy

Due to the near complete oral bioavailability of flecainide, switching from IV flecainide application to PO flecainide application is possible without a new dose adjustment. As a rule, an interval of 8 to 12 hours should elapse between the completion of IV administration and the ingestion of the first dose. Because flecainide has a narrow therapeutic spectrum, close follow up monitoring is required.

Method of Administration

For oral use. Take Flecainide Acetate Oral Solution with a glass of water.

In order to avoid the possibility of food affecting the absorption of the drug, flecainide should be taken on an empty stomach or one hour before food.

Measuring your dose

The cup in the pack delivers:

- 30 ml with dosage marks at 2.5ml, 5ml, 10ml and 15ml, 20ml.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

- Flecainide is contraindicated in cardiac failure and in patients with a history of myocardial infarction who have either asymptomatic ventricular ectopics or asymptomatic non-sustained ventricular tachycardia.

- Patients with long standing atrial fibrillation in whom there has been no attempt to convert to sinus rhythm

- Patients with reduced or impaired ventricular function, cardiogenic shock, severe bradycardia (less than 50 bpm), severe hypotension.

- Use in combination with Class I antiarrhythmic drugs. (Sodium channel blockers)

- In patients with haemo dynamically significant valvular heart disease.

- Unless pacing rescue is available, flecainide must not be given to patients with sinus node dysfunction, atrial condition defects, second degree or greater atrio-ventricular block, bundle branch block or distal block.

- Patients with asymptomatic or mildly symptomatic ventricular arrhythmias must not be given flecainide.

- Use in patients with significant electrolyte imbalance (see section 4.4).

- Known Brugada syndrome.

4.4 Special warnings and precautions for use

Treatment with oral flecainide should be under direct hospital or specialist supervision for patients with:

• AV nodal reciprocating tachycardia; arrhythmias associated with Wolff-Parkinson-White Syndrome and similar conditions with accessory pathways.

• Paroxysmal atrial fibrillation in patients with disabling symptoms.

Flecainide has been shown to increase mortality risk of post-myocardial infarction patients with asymptomatic ventricular arrhythmia.

Flecainide, like other antiarrhythmics, may cause proarrhythmic effects, i.e. it may cause the appearance of a more severe type of arrhythmia, increase the frequency of an existing arrhythmia or the severity of the symptoms (see section 4.8).

Flecainide should be avoided in patients with structural heart disease or abnormal left ventricular function (see section 4.8).

Flecainide should be used with caution in patients with acute onset of atrial fibrillation following cardiac surgery.

Treatment for patients with other indications should continue to be initiated in hospital.

An acceleration of the ventricular rate of atrial fibrillation in case of therapy failure has been reported.

Flecainide has a selective effect that increases the refractory period of the anterograde, and especially, the retrograde pathways.

Flecainide prolongs the QT interval and widens the QRS complex by 12-20 %. The effect on the JT interval is insignificant. Nevertheless, there have been reports of prolongation of the JT interval of up to 4%. This action is less marked than that observed with the class I antiarrhythmic drugs however.

A Brugada syndrome may be unmasked due to flecainide therapy. In the case of development of ECG changes during treatment with flecainide that may indicate Brugada syndrome, consideration to discontinue the treatment should be made.

Since flecainide elimination from the plasma can be markedly slower in patients with significant hepatic impairment, flecainide should not be used in such patients unless the potential benefits outweigh the risks. Plasma level monitoring is recommended.

Flecainide should be used with caution in patients with impaired renal function (creatinine clearance $\leq$ 35 ml/min/1.73 m2) and therapeutic drug monitoring is recommended as increase of plasma levels may also result from renal impairment due to a reduced clearance of flecainide.

The rate of flecainide elimination from plasma may be reduced in the elderly. This should be taken into consideration when making dose adjustments.

Flecainide is not recommended in children under 12 years of age, as there is insufficient evidence of its use in this age group.

Electrolyte disturbances (e.g. hypo- and hyperkalaemia) should be corrected before using flecainide (see 4.5 for some drugs causing electrolyte disturbances).

Severe bradycardia or pronounced hypotension should be corrected before using flecainide.

Flecainide is known to increase endocardial pacing thresholds, i.e. to decrease endocardial pacing sensitivity. This effect is reversible and is more marked on the acute pacing threshold than on the chronic. Flecainide should thus be used with caution in all patients with permanent pacemakers or temporary pacing electrodes, and should not be administered to patients with existing poor thresholds or non-programmable pacemakers unless suitable pacing rescue is available.

Generally, a doubling of either pulse width or voltage is sufficient to regain capture, but it may be difficult to obtain ventricular thresholds less than 1 Volt at initial implantation in the presence of flecainide.

The minor negative inotropic effect of flecainide may assume importance in patients predisposed to cardiac failure. Difficulty has been experienced in defibrillating some patients. Most of the cases reported had pre-existing heart disease with cardiac enlargement, a history of myocardial infarction, arterio-sclerotic heart disease and cardiac failure.

Dairy products (milk, infant formula and possibly yoghurt) may reduce the absorption of flecainide in children and infants. Flecainide is not approved for use in children below the age of 12 years, however flecainide toxicity has been reported during treatment with flecainide in children who reduced their intake of milk, and in infants who were switched from milk formula to dextrose feedings.

Liquid flecainide formulations may have a local anaesthetic effect on the mouth. Patients should be advised to avoid eating until any anaesthetic effect has worn off.

Flecainide as a narrow therapeutic index drug requires caution and close monitoring when switching a patient to a different formulation.

For further warnings and precautions please refer to 4.5.

Excipient Warnings

This product contains:

- Liquid Maltitol - Patients with rare hereditary problems of fructose intolerance should not take this medicine.
- This medicine contains less than 1 mmol sodium (23 mg) per 5 ml, that is to say essentially ‘sodium-free’.

4.5 Interaction with other medicinal products and other forms of interaction

Flecainide is a class I anti-arrhythmic and interactions are possible with other anti-arrhythmic drugs where additive effects may occur or where drugs interfere with the metabolism of flecainide.

The simultaneous administration of flecainide and antiarrhythmic of other classes should only be performed if there is a noticeable therapeutic effect and requires close clinical control and electrocardiogram (ECG) monitoring.

The following known categories of drugs may interact with flecainide:

Class I antiarrhythmics: Flecainide should not be administered concomitantly with other class I antiarrythmics.

Class II antiarrhythmics: The possibility of additive negative inotropic effects of Class II antiarrhythmics, i.e. beta-blockers, with flecainide should be recognised.

Class III antiarrhythmics: If flecainide is given in the presence of amiodarone the usual flecainide dosage should be reduced by 50% and the patient

monitored closely for adverse effects. Plasma level monitoring is strongly recommended in these circumstances.

Class IV antiarrhythmics: The use of flecainide with calcium channel blockers, e.g. verapamil, should be considered with caution.

Life-threatening or even lethal adverse events due to interactions causing increased plasma concentrations may occur (see section 4.9). Flecainide is metabolized by CYP2D6 to a large extent, and concurrent use of drugs inhibiting (e.g. antidepressants, neuroleptics, propranolol, ritonavir, some antihistamines) or inducing (e.g. phenytoin, phenobarbital, carbamazepine) this iso-enzyme can increase or decrease plasma concentrations of flecainide, respectively (see below).

In a study of healthy subjects treated simultaneously with flecainide and propranolol, the plasma levels were increased with about 20% and 30%, respectively.

An increase of plasma levels may also result from renal impairment due to a reduced clearance of flecainide (see section 4.4).

Hypokalaemia but also hyperkalaemia or other electrolyte disturbances should be corrected before administration of flecainide. Hypokalaemia may result from the concomitant use of diuretics, corticosteroids or laxatives.

Antihistamines: Increased risk of ventricular arrhythmias with mizolastine, astemizole and terfenadine (avoid concomitant use).

Antivirals: Plasma concentrations are increased by ritonavir, lopinavir and indinavir (increased risk of ventricular arrhythmias) (avoid concomitant use).

Antidepressants: Fluoxetine, paroxetine and other antidepressants increases plasma flecainide concentration; increased risk of arrhythmias with tricyclics; manufacturer of reboxetine advises caution.

Antiepileptics: Limited data in patients receiving known enzyme inducers (phenytoin, phenobarbital, carbamazepine) indicate only a 30% increase in the rate of flecainide elimination.

Antipsychotics: Clozapine, haloperidol and risperidone – increased risk of arrhythmias.

Antimalarials: Quinine, quinidine and halofantrine increase plasma concentrations of flecainide.

Antifungals: Terbinafine may increase plasma concentrations of flecainide resulting from its inhibition of CYP2D6 activity.

Diuretics: Class effect due to hypokalaemia giving rise to cardiotoxicity.

H2 antihistamines (for the treatment of gastric ulcers): The H2 antagonist cimetidine inhibits metabolism of flecainide. In healthy subjects receiving cimetidine (1 g daily) for 1 week, the AUC of flecainide increased by about 30 % and the half-life increased by about 10 %.

Antismoking aids: Co-administration of bupropion (metabolised by CYP2D6) with flecainide should be approached with caution and should be initiated at the lower end of the dose range of the concomitant medication. If bupropion is

added to the treatment regimen of a patient already receiving flecainide, the need to decrease the dose of the original medication should be considered.

Cardiac glycosides: Flecainide can cause the plasma digoxin level to rise by about 15%, which is unlikely to be of clinical significance for patients with plasma levels in the therapeutic range. It is recommended that the digoxin plasma level in digitalised patients should be measured not less than six hours after any digoxin dose, before or after administration of flecainide.

Anticoagulants: The treatment with flecainide is compatible with the use of oral anticoagulants.

If flecainide and activated charcoal (e.g. charcoal tablets) are administered at the same time, it should be considered that in these cases the absorption of flecainide from the intestine and thus the effectiveness of flecainide could be affected.

4.6 Fertility, pregnancy and lactation

Pregnancy

There is no evidence as to drug safety in human pregnancy. In New Zealand White rabbits, high doses of flecainide caused some foetal abnormalities, but these effects were not seen in Dutch Belted rabbits or rats (see section 5.3). The relevance of these findings to humans has not been established. Data have shown that flecainide crosses the placenta to the foetus in patients taking flecainide during pregnancy. Flecainide should only be used in pregnancy if the benefit outweighs the risks. If flecainide is used during pregnancy maternal flecainide plasma levels should be monitored throughout pregnancy.

Breast-feeding

Flecainide is excreted in human breast milk and appears in concentrations similar to those in maternal blood. Plasma concentrations obtained in a nursing infant are 5-10 times lower than therapeutic drug concentrations (see section 5.2). Although the risk of adverse effects to the nursing infant is very small, flecainide should only be used during lactation if the benefit outweighs the risks.

Fertility

There are no human data on the influence of flecainide on fertility. In animal experiments research showed that flecainide had no effect on fertility.

4.7 Effects on ability to drive and use machines

Flecainide acetate has moderate influence on the ability to drive and use machines. Driving ability and operation of machinery may be affected by adverse reactions such as dizziness and visual disturbances, if present.

4.8 Undesirable effects

Summary of the safety profile

Like other anti-arrhythmics flecainide can have the effect of inducing arrhythmia.

The existing arrhythmia may worsen or a new arrhythmia may occur. The risk of pro arrhythmic effects is most likely in patients with a structural heart disease and/or significant left ventricular impairment.

The most commonly occurring cardiovascular adverse effects are second and third degree AV block, bradycardia, cardiac failure, chest pain, myocardial infarction, hypotension, sinus arrest, tachycardia (AT and VT) and palpitations.

The most common adverse effects are dizziness and visual disturbances that occur in about 15 % of the patients receiving treatment. These adverse effects are usually transient and disappear upon discontinuing or reducing the dosage. The following list of adverse effects are based on experiences from clinical trials and reported after marketing.

Very common ≥1/10

Common ≥1/100 to <1/10

Uncommon ≥1/1000 to <1/100

Rare ≥1/10,000 to <1/1000

Very rare <1/10,000 uncommon: red blood cell count decreased, white blood cell count decreased and platelet count decreased

Tabulated summary of adverse reactions

System Organ Class	Frequency	Adverse reaction
Blood And Lymphatic System Disorders	Uncommon	red blood cell count decreased, white blood cell count decreased and platelet count decreased
Immune System Disorders	Very Rare	antinuclear antibody increased with and without systemic inflammation
Metabolism And Nutrition Disorders	Not Known	Anorexia
Psychatric Disorders	Uncommon	Impotence, decreased libido, depersonalization/derealisation disorder, euphoric mood, increased dream activity, apathy, stupor
	Rare	hallucination, depression, confusional state, anxiety, amnesia,

		insomnia
Nervous System Disorders	Very Common	dizziness, vertigo and light-headedness which are usually transient
	Rare	paraesthesia, ataxia, hypoaesthesia, hyperhidrosis, syncope, tremor, flushing, somnolence, headache, neuropathy peripheral, convulsion, dyskinesia, paresis and speech disorders
	Not Known	*local anaesthesia to the mouth
Eye Disorders	Very Common	visual impairment, such as diplopia and vision blurred
	Uncommon	eye irritation, photophobia and nystagmus
	Very Rare	corneal deposits
Ear And Labyrinth Disorders	Rare	tinnitus, vertigo
Cardiac Disorders	Common	Proarrhythmia (most likely in patients with structural heart disease).
	Uncommon	hypertension. Patients with atrial flutter can develop a 1:1 AV conduction with increased heart rate.
	Not Known	(cannot be estimated from the available data): atrioventricular block-second-degree and atrioventricular block third degree, cardiac arrest, bradycardia, cardiac failure/ cardiac failure congestive, chest pain, hypotension, myocardial infarction, palpitations, sinus arrest, and tachycardia (AT or VT) or ventricular fibrillation.. Demasking of a pre-existing Brugada syndrome. Dose-related increases in PR and QRS intervals may occur (see section 4.4). Altered pacing threshold (see section 4.4).
Respiratory, Thoracic And Mediastinal Disorders	Common	dyspnoea
	Uncommon	bronchospasm
	Rare	pneumonitis
	Not Known	(cannot be estimated from the available data): pulmonary fibrosis, interstitial lung disease
Gastrointestinal	Uncommon	nausea, vomiting, constipation,

Disorders		abdominal pain, decreased appetite, diarrhoea, dyspepsia, flatulence, dry mouth, dysgeusia.
Hepatobiliary Disorders	Rare	hepatic enzymes increased with and without jaundice
	Not Known	(cannot be estimated from the available data): hepatic dysfunction
Skin And Subcutaneous Tissue Disorders	Uncommon	itching, exfoliative dermatitis, dermatitis allergic, including rash, alopecia
	Rare	serious urticaria
	Very Rare	photosensitivity reaction
Musculoskeletal And Connective Tissue Disorders	Not Known	arthralgia, myalgia
Renal And Urinary Disorders	Uncommon	polyuria, urinary retention
General Disorders And Administration Site Conditions	Common	asthenia, fatigue, pyrexia, oedema, malaise
	Uncommon	swollen lips, tongue and mouth

*This adverse effect relates specifically to the liquid formulation.

Although no cause and effect relationship has been established, it is advisable to discontinue flecainide administration in patients in whom unexplained jaundice or signs of liver dysfunction or blood dyscrasias occur, in order to eliminate flecainide as a possible cause.

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: http://www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Overdose with flecainide is a potentially life-threatening medical emergency. Increased drug susceptibility and plasma levels exceeding therapeutic levels may also result from drug interaction (see section 4.5). Overdose can lead to hypotension, seizures, bradycardia, conduction delays (sinoarterial or AV block) and asystole. The QRS and QT intervals are extended and ventricular arrhythmias may occur. Flecainide can slow or reverse atrial fibrillation in atrium flutter with fast conduction.

No specific antidote is known. There is no known way to rapidly remove flecainide from the system. Neither dialysis nor haemoperfusion is effective.

Treatment should be supportive and may include removal of unabsorbed drug from the GI tract. 8.4% intravenous sodium bicarbonate reduces the activity of flecainide. Further measures may include inotropic agents or cardiac stimulants such as dopamine, dobutamine or isoproterenol as well as mechanical ventilation and circulatory assistance (e.g. ballon pumping). Temporarily inserting a transvenous pacemaker in the event of conduction block should be considered. Assuming a plasma half-life of approximately 20 h, these supportive treatments may need to be continued for an extended period of time. Forced diuresis with acidification of the urine theoretically promotes drug excretion. Intravenous fat emulsion and Extra Corporal Membrane (ECMO) could be considered on a case-by-case basis.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antiarrhythmics, class IC, Flecainide

ATC code: C01 BC 04

Flecainide acetate is a Class IC antiarrhythmic agent used for the treatment of severe symptomatic life-threatening ventricular arrhythmias and supraventricular arrhythmias

Electrophysiologically, flecainide is a local anaesthetic-type (Class IC) of antiarrhythmic compound. It is an amide type of local anaesthetic, being structurally related to procainamide and encainide in so far as these agents are also benzamide derivatives.

The characterisation of flecainide as a Class IC compound is based on a triad of features: marked depression of the fast sodium channel in the heart; slow onset and offset kinetics of inhibition of the sodium channel (reflecting slow attachment to and dissociation from sodium channels); and the differential effect of the drug on the action potential duration in ventricular muscle versus Purkinje fibres, having no effect in the former and markedly shortening it in the latter. This composite of properties leads to a marked depression in conduction velocity in fibres dependant on the fast-channel fibres for depolarisation but with a modest increase in the effective refractory period when tested in isolated cardiac tissues. These electrophysiological properties of flecainide acetate may lead to prolongation of the PR-interval and QRS duration on the ECG.

Flecainide acetate generally does not change heart rate, although it can rarely be associated with the appearance of bradycardia or tachycardia. A slight negative inotropic effect was also observed, with a reduction in the ejection

fraction after a single dose of 200 mg. Increases or decreases in ejection fraction have been observed during chronic administration of therapeutic doses.

At very high concentrations flecainide exerts a weak depressant effect on the slow channel in the myocardium. This is accompanied by a negative inotropic effect.

5.2 Pharmacokinetic properties

Absorption

Flecainide is almost completely absorbed after oral administration and does not undergo extensive first-pass metabolism. The bioavailability from flecainide acetate tablets has been reported to be about 90%.

The therapeutic plasma concentration range is generally accepted as 200 to 1000ng per ml. Given intravenously the mean time to achieve peak serum concentration was 0.67 hours and the mean bioavailability was 98%, compared with 1 hour and 78% for an oral solution and 4 hours and 81% for a tablet. The steady-state blood levels are reached 3-5 days after the start of therapy: there has been no demonstration of accumulation after prolonged treatment.

In patients with dosing restrictions (see section 4.2), due to the associated change in metabolism and excretion of flecainide, 6 - 8 days, and in exceptional cases up to 20 days, may elapse before steady-state conditions are reached..

Distribution

Flecainide is about 40% bound to plasma proteins. Flecainide passes the placenta and is excreted in breast milk.

Biotransformation

Flecainide is extensively metabolised (subject to genetic polymorphism), the 2 major metabolites being m-O-dealkylated flecainide and m-O-dealkylated lactam of flecainide, both of which may have some activity. Its metabolism appears to involve the cytochrome P450 isoenzyme CYP2D6, which shows genetic polymorphism.

Elimination

Flecainide is excreted mainly in the urine, approximately 30% as unchanged drug and the remainder as metabolites. About 5% is excreted in the faeces.

Elimination of flecainide depends on kidney function. An increase in kidney dysfunction is accompanied by a reduction in the excreted amount of unaltered drug and an increase in the plasma half-life time. In the case of simultaneous increase of flecainide metabolism, the relationship between renal clearance and drug elimination from plasma is not linear.

The elimination of flecainide from plasma may be decreased in the elderly compared to younger people, which should be taken into consideration when making dose adjustments.

Excretion of flecainide is decreased in renal failure, liver diseases, heart failure, and in alkaline urine. Haemodialysis removes only about 1% of unchanged flecainide.

The elimination half-life of flecainide is about 20 hours.

5.3 Preclinical safety data

The only Non-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC are the following effects found on reproduction.

Flecainide has not shown significant systemic target organ toxicity in repeated dose studies in animals. It was neither mutagenic nor carcinogenic in rats and mice. Flecainide can cross the placenta and is excreted in breast milk. At high doses it has shown fetotoxicity in rats and at high doses caused fetal abnormalities in New Zealand white rabbits, but not in Dutch Belted rabbits or rats. The relevance of these findings to humans has not yet been established.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric Acid Monohydrate E330

Sodium Citrate E331

Strawberry Flavour

Sucralose E995

Liquid Maltitol E965

Purified Water

6.2 Incompatibilities

None stated

6.3 Shelf life

24 months.

Use within 30 days of opening the bottle.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Bottle: Amber (Type III glass)

Closure: HDPE, EPE wadded, child resistant closure

Oral dosing device: 30 ml cup

Pack size: 150ml

6.6 Special precautions for disposal

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

7 MARKETING AUTHORISATION HOLDER

Rosemont Pharmaceuticals Ltd

Rosemont House

Yorkdale Industrial Park

Braithwaite Street

Leeds

LS11 9XE

UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 00427/0310

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

19/01/2026