**Axalid 25/50/75/100/150/200/225/300mg hard capsules**

**POSSIBLE ADVERSE REACTIONS**

**Cardiovascular System**
- Hypotension
- Tachycardia
- Chest pain
- Peripheral oedema

**Central Nervous System**
- Fatigue
- Somnolence
- Dizziness
- Nausea
- Anxiety
- Dizziness
- Asthenia
- Confusion
- Parasthesis
- Tinnitus

**Gastrointestinal Tract**
- Nausea
- Vomiting
- Diarrhoea
- Abdominal pain
- Anorexia

**Liver and Biliary System**
- Transient increases in hepatic liver enzymes

**Musculoskeletal System**
- Arthralgia
- Myalgia
- Muscle twitching

**Respiratory System**
- Asthma
- Pharyngitis

**Skin**
- Rash
- Urticaria
- Pruritus
- Hyperhidrosis

**Vascular Disorders**
- Hypotension

**Other**
- Anaphylaxis
- Angioedema

**INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION**

**PREGNANCY**

Pregabalin has shown a small increase in risk of suicidal ideation and behaviour in clinical studies in children with ADHD, and a small increase in suicidal ideation in postmarketing data in patients with other indications. There is a risk of postmarketing reports of suicide attempts and suicidal ideation, and should be considered, alongside the potential benefit of therapy, when treating children and adolescents with pregabalin. Patients (and caregivers of patients) should be advised to seek medical advice should signs of suicidal ideation or behaviour emerge.

**NURSING MOTHERS**

Pregabalin is excreted in breast milk. The safety and efficacy of pregabalin in nursing mothers has not been established. Breastfeeding is not recommended in women who are treated with pregabalin.

**INTERACTION WITH OTHER MEDICINAL PRODUCTS**

**INTERACTION WITH ALCOHOL AND OTHER SUBSTANCES**

Alcohol and pregabalin should be avoided because alcohol misuse, abuse or dependence may impair the ability to perform activities involving physical or mental coordination. The risk of abuse or dependence is increased in those with a history of substance abuse. For patients (and caregivers of patients) who develop suicidal ideation or suicidal behaviour, the potential for alcohol misuse, abuse or dependence (development of tolerance, drug-seeking behaviour) have been reported.

**INTERACTION WITH OTHER MEDICINAL PRODUCTS**

### PROTOCOL

**Incidence**

Cases of encephalopathy have been reported, mostly in patients with underlying conditions that may prolong the recovery phase (e.g. metabolic, haematological, immunological or neurological disorders). The symptoms of encephalopathy are highly variable and include altered level of consciousness, seizures, confusion, hallucinations, delirium, coma, coma-like state, and convulsions. The clinical presentation may be acute or subacute. The early diagnosis and prompt discontinuation of pregabalin are required for the treatment of encephalopathy. The safety of pregabalin in children below the age of 12 years and in adolescents (12-17 years of age) has not been established.

**PREGNANCY**

Pregabalin is not recommended for use during pregnancy unless clearly necessary (if the benefit to the mother clearly outweighs the potential risk to the foetus). Pregabalin should be discontinued before conception if possible and before any planned pregnancy. There are no clinical data on the effects of pregabalin on female fertility.

**REPRODUCTION TOXICITY (see section 5.3). The potential risk for humans is unknown.**

**UNDESIREABLE EFFECTS**

### Epicutaneous hypersensitivity (including anaphylaxis), angioedema, urticaria, pruritus, rash, dermatitis, tremor, dizziness, headache, nausea, anxiety, diaphoresis, flu syndrome, nausea, vomiting, pyrexia, confusion, hyperhidrosis and dizziness suggestive of physical dependence. The patient should be informed about this at the start of the treatment. Concomitant intake of alcohol, sedative and other hypnotics should be avoided during pregabalin use or should be discontinued at least 1 week before starting pregabalin treatment. Concerning discontinuation of long-term treatment of pregabalin, data suggest that the incidence and severity of withdrawal symptoms may be dose-related.

**ADVERSE REACTIONS**

### Astaxan
disorders, or angioedema (including urticaria) requiring hospitalisation or resulting in persistent or significant disability or incapacity, or cases in which the drug is life-threatening or when there is a high probability of recurrence in the absence of treatment. Cases of anaphylaxis, angioedema or urticaria (including anaphylaxis) requiring hospitalisation or resulting in persistent or significant disability or incapacity, or cases in which the drug is life-threatening or when there is a high probability of recurrence in the absence of treatment.

**Hypersensitivity**

Cases of angioedema have been reported, mostly in patients with underlying conditions that may prolong the recovery phase (e.g. metabolic, haematological, immunological or neurological disorders). The symptoms of angioedema are highly variable and include swelling of the face, tongue, larynx, lips, pharynx, oesophagus, and oedema of the upper airway. The clinical presentation may be acute or subacute. The early diagnosis and prompt discontinuation of pregabalin are required for the treatment of angioedema. The safety of pregabalin in children below the age of 12 years and in adolescents (12-17 years of age) has not been established.

**PRINCIPAL ADVERSE REACTIONS FOR USES**

### Pregnancy

Pregabalin is not recommended for use during pregnancy unless clearly necessary (if the benefit to the mother clearly outweighs the potential risk to the foetus). Pregabalin should be discontinued before conception if possible and before any planned pregnancy. There are no clinical data on the effects of pregabalin on female fertility.

**FERTILITY, PREGNANCY AND LACTATION**

**Reporting of suspected adverse reactions**

Adverse reactions should also be reported to the Kent Pharmaceuticals Limited on 184 (01625) 355 574 or medical@icovital.com.

**Date of last SMEC revision:** 04/10/2017

**MARKETING AUTHORITY HOLDER:** Kent Pharmaceuticals Limited

**MARKETING AUTHORITY NUMBER:** PL 02581806 - 103

**LEGAL CATEGORY:** POM

**DATE OF PREPARATION:** 13/01/2017

**UK18/00651 UK2017/JAN02**

**Urgent attention:** Please contact the Medical Information Team for medical information, please contact Kent Pharmaceuticals Limited on 0845 838 0790.

**For a copy of the SMEC or further information:** Please contact medical@icovital.com or contact your local representative.