SCHEDULING STATUS: S5

1 NAME OF THE MEDICINE

ALOND® 25 mg Capsules

ALOND® 75 mg Capsules

ALOND® 150 mg Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

ALOND 25 mg: Each capsule contains 25 mg pregabalin.

ALOND 75 mg: Each capsule contains 75 mg pregabalin.

ALOND 150 mg: Each capsule contains 150 mg pregabalin.

Contains sugar (lactose monohydrate).

Excipients with known effect

Each ALOND 25 mg capsule contains 35 mg lactose monohydrate.

Each ALOND 75 mg capsule contains 8,25 mg lactose monohydrate.

Each ALOND 150 mg capsule contains 16,5 mg lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsules

ALOND 25 mg: White, opaque, hard gelatine capsule, marked ”VTRS” on the cap and “PGN 25” on the body with black ink.

ALOND 75 mg: White (body) and orange (cap), opaque, hard gelatine capsule, marked ”VTRS” on the cap and “PGN 75” on the body with black ink.

ALOND 150 mg: White, opaque, hard gelatine capsule, marked ”VTRS” on the cap and “PGN 150” on the body with black ink.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Neuropathic pain

ALOND is indicated for the treatment of adult patients with neuropathic pain due to Herpes zoster infections and diabetes.

4.2 Posology and method of administration

Posology

The recommended starting dose for ALOND is 75 mg twice daily (150 mg/day), with or without food. Based on individual patient response and tolerability, the dose may be increased to 150 mg twice daily after an interval of 3 to 7 days.

In accordance with current clinical practice, if ALOND has to be discontinued, it is recommended this should be done gradually over a minimum of 1 week.

Special populations

Renal impairment

ALOND is eliminated from the systemic circulation primarily by renal excretion as unchanged medicine. As ALOND clearance is directly proportional to creatinine clearance (see section 5.2, *Pharmacokinetics in special populations – Renal impairment*), dosage reduction in patients with compromised renal function must be individualised according to creatinine clearance (CL_{cr}), as indicated in Table 1 determined using the following formula:

$$CL_{cr}\ (mL/min) = \frac{(140 - age[years]) \times Weight\ (kg)}{0{,}82 \times Serum\ creatinine\ (\mu mol/l)}$$

*For females multiply the CL_{cr} by 0,85

ALOND is removed effectively from plasma by haemodialysis (50 % of medicine in 4 hours). For patients receiving haemodialysis, the ALOND daily dose should be adjusted based on renal function. In addition to the daily dose, a supplementary dose should be given immediately following every 4-hour haemodialysis treatment (see Table 1).

Table 1. ALOND dosage adjustment based on renal function

Creatinine clearance (CL_{cr}) (mL/min)	**Total ALOND daily dose***	**Dose regimen**

	Starting dose (mg/day)	**Maximum dose (mg/day)**	
≥ 60	150	300	BD
30 – 60	75	150	OD or BD
15 – 30	25 – 50	75	OD or BD
< 15	25	25 – 50	OD
Supplementary dosage following haemodialysis (mg)			
	25	50	Single dose[+]

BD = Twice daily

OD = Once daily

*Total daily dose (mg/day) should be divided as indicated by dose regimen to provide mg/dose

[+]Supplementary dose is a single additional dose

Hepatic impairment

No dosage adjustment is required for patients with hepatic impairment (see section 5.2, *Pharmacokinetics in special populations – Hepatic impairment*).

Elderly population (over 65 years of age)

No dosage adjustment is necessary for elderly patients unless their renal function is compromised, see Table 1.

Paediatric population

The safety and effectiveness of ALOND in patients below the age of 18 years with neuropathic pain has not been established.

Method of administration

For oral use.

ALOND is given orally with or without food.

4.3 Contraindications

Hypersensitivity to pregabalin or to any of the excipients of ALOND (listed in section 6.1).

4.4 Special warnings and precautions for use

Diabetic patients

In accordance with current clinical practice, some diabetic patients who gain weight on ALOND treatment may need to adjust hypoglycaemic medicines.

Hypersensitivity reactions

There have been reports in the post-marketing experience of hypersensitivity reactions, including cases of angioedema and urticaria. ALOND should be discontinued immediately if symptoms of angioedema, such as facial, perioral or upper airway swelling occur.

Severe cutaneous adverse reactions (SCARs)

SCARs including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), which can be life-threatening or fatal, have been reported rarely in association with ALOND treatment. At the time of prescription, patients should be advised of the signs and symptoms and monitored closely for skin reactions. If signs and symptoms suggestive of these reactions appear, ALOND should be withdrawn immediately, and an alternative treatment considered (as appropriate).

Dizziness, somnolence, loss of consciousness, confusion and mental impairment

ALOND treatment has been associated with dizziness and somnolence, which could increase the occurrence of accidental injury (fall) in the elderly population. There have been post-marketing reports of loss of consciousness, confusion, and mental impairment. Therefore, patients should be advised to exercise caution until they are familiar with the potential effects of the medicine (see section 4.8).

Vision-related effects

In controlled trials, a higher proportion of patients treated with ALOND reported blurred vision than did patients treated with placebo, which resolved in a majority of cases with continued dosing. In the clinical studies where ophthalmologic testing was conducted, the incidence of visual acuity reduction and visual field changes was greater in ALOND-treated patients than in placebo-treated patients; the incidence of fundoscopic changes was greater in placebo-treated patients.

In the post-marketing experience, visual adverse reactions have also been reported, including loss of vision, visual blurring or other changes of visual acuity, many of which were transient. Discontinuation of ALOND may result in resolution or improvement of these visual symptoms.

Respiratory depression

There have been reports of severe respiratory depression in relation to ALOND use. Patients with

compromised respiratory function, respiratory or neurological disease, renal impairment, concomitant use of CNS depressants and the elderly may be at higher risk of experiencing this severe adverse reaction. Dose adjustments may be necessary in these patients (see section 4.2).

Suicidal ideation and behaviour

Suicidal ideation and behaviour have been reported in patients treated with ALOND in several indications. Cases of suicidal ideation and behaviour have been observed in patients treated with ALOND in the post-marketing experience (see section 4.8). An epidemiological study using a self-controlled study design (comparing treatment periods with non-treatment periods within an individual) showed evidence of an increased risk of new onset of suicidal behaviour and death by suicide in patients treated with ALOND. A meta-analysis of randomised placebo-controlled studies of anti-epileptic medicines has also shown a small increased risk of suicidal ideation and behaviour. The mechanism of this risk is not known, and the available data do not exclude the possibility of an increased risk for ALOND.

Therefore, patients should be monitored for signs of suicidal ideation and behaviours and appropriate treatment should be considered. Patients (and caregivers) should be advised to seek medical advice should signs of suicidal ideation or behaviour emerge. Discontinuation of ALOND treatment should be considered in case of suicidal ideation and behaviour.

Concomitant use with opioids

Caution is advised when prescribing ALOND concomitantly with opioids due to risk of CNS depression. In an observational study of opioid users, those patients who took ALOND concomitantly with an opioid had an increased risk for opioid-related death compared to opioid use alone (adjusted odds ratio [aOR], 1.68 [95% CI, 1.19 to 2.36]).

Misuse, abuse potential or dependence

ALOND can cause drug dependence, which may occur at therapeutic doses. Cases of abuse, misuse and dependence have been reported. Patients with a history of substance abuse and/or psychiatric disorders may be at higher risk for ALOND misuse, abuse and dependence and ALOND should be used with caution in such patients. Before prescribing ALOND, the patient’s risk of misuse, abuse or dependence should be carefully evaluated.

Patients treated with ALOND should be monitored for symptoms of ALOND misuse, abuse or

dependence, such as development of tolerance, dose escalation and drug-seeking behaviour.

Withdrawal symptoms

After discontinuation of short-term and long-term treatment with ALOND, withdrawal symptoms have been observed in some patients. The following events have been reported: insomnia, headache, nausea, anxiety and diarrhoea (see section 4.8).

Renal failure

Although the effects of discontinuation on the reversibility of renal failure have not been systematically studied, improved renal function following discontinuation or dose reduction of ALOND has been reported (see section 4.8). Renal failure has occurred.

Congestive heart failure

There have been post-marketing reports of congestive heart failure or deterioration of heart failure in some patients receiving ALOND. In short-term trials of patients without clinically significant heart or peripheral vascular disease, there was no apparent association between peripheral oedema and cardiovascular complications such as hypertension or congestive heart failure. ALOND should be used with caution in patients with congestive heart failure (see section 4.8).

Women of childbearing potential/Contraception

ALOND use in the first trimester of pregnancy may cause major birth defects in the unborn child. ALOND should not be used during pregnancy unless the benefit to the mother clearly outweighs the potential risk to the foetus. Women of childbearing potential must use effective contraception during treatment (see section 4.6).

Lactose intolerance

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

4.5 Interaction with other medicines and other forms of interaction

Since ALOND is predominantly excreted unchanged in the urine, undergoes negligible metabolism in humans (< 2 % of a dose recovered in urine as metabolites), does not inhibit medicine metabolism *in vitro*, and is not bound to plasma proteins, ALOND is unlikely to produce, or be subject to, pharmacokinetic interactions.

***In vivo* studies and population pharmacokinetic analysis**

Accordingly, in *in vivo* studies no clinically relevant pharmacokinetic interactions were observed between ALOND and phenytoin, carbamazepine, valproic acid, lamotrigine, gabapentin, lorazepam, oxycodone or ethanol. In addition, population pharmacokinetic analysis indicated that the 3 commonly used medicine classes, oral antidiabetics, diuretics and insulin, and the commonly used anti-epileptic medicines, phenytoin, carbamazepine, valproic acid, lamotrigine, phenobarbital, tiagabine, and topiramate, had no clinically significant effect on pregabalin clearance. Similarly, these analyses indicated that ALOND had no clinically significant effect on the clearance of phenytoin, carbamazepine, valproic acid, lamotrigine, topiramate and phenobarbital.

Oral contraceptives, norethisterone and/or ethinyl oestradiol

Co-administration of ALOND with the oral contraceptives norethisterone and/or ethinyl estradiol does not influence the steady-state pharmacokinetics of either medicine.

Central nervous system influencing medicines

Multiple oral doses of ALOND co-administered with oxycodone, lorazepam, or ethanol did not result in clinically important effects on respiration. ALOND appears to be additive in the impairment of cognitive and gross motor function caused by oxycodone. ALOND may potentiate the effects of ethanol and lorazepam.

In post-marketing experience, there are reports of respiratory failure, coma and deaths in patients taking ALOND and other CNS depressant medicines, including in patients who are substance abusers.

There are post-marketing reports of events related to reduced lower gastrointestinal tract function (e.g. intestinal obstruction, paralytic ileus, constipation) when ALOND was co-administered with medicines that have the potential to produce constipation, such as opioid analgesics.

4.6 Fertility, pregnancy and lactation

Women of childbearing potential/ Contraception in males and females

Women of childbearing potential have to use effective contraception during treatment (see section 4.4).

Pregnancy

There is a limited amount of data on the use of ALOND in pregnant women.

Data from a Nordic observational study, which included more than 2 700 pregnancies exposed to

ALOND based on routinely collected data from administrative and medical registers, do not suggest substantially increased risks of major congenital malformations, adverse birth outcomes, or abnormal postnatal neurodevelopmental outcomes in ALOND-exposed pregnancies.

Major congenital malformations

The adjusted prevalence ratios (aPRs) and 95 % confidence intervals (CI) in the standard meta-analysis for first-trimester ALOND monotherapy-exposed vs. unexposed to anti-epileptic drugs was 1,13 (0,96 – 1,33).

Birth and postnatal neurodevelopmental outcomes

There were no statistically significant findings for stillbirth, low birth weight, preterm birth, small for gestational age, low Apgar score, and microcephaly.

In paediatric population exposed *in utero*, the study did not provide evidence of an increased risk for attention deficit hyperactivity disorder (ADHD), autism spectrum disorders (ASD) and intellectual disabilities.

Studies in animals have shown reproductive toxicity. Therefore, ALOND should not be used during pregnancy.

Breastfeeding

ALOND is excreted into human milk (see section 5.2). The effect of ALOND on newborns/infants is unknown. Because the safety of ALOND in infants is not known, breastfeeding is not recommended during treatment with ALOND.

4.7 Effects on ability to drive and use machines

ALOND frequently causes dizziness and somnolence. Head and body injuries and road traffic incidents have also been reported in patients treated with ALOND. Therefore, patients are advised not to drive, operate complex machinery or engage in other potentially hazardous activities until it is known whether ALOND affects their ability to perform these activities.

4.8 Undesirable effects

Summary of the safety profile

The ALOND clinical programme involved over 8 900 patients who were exposed to ALOND, of whom

over 5 600 were in double-blind placebo-controlled trials. The most commonly reported adverse reactions were dizziness and somnolence which were dose related. Adverse reactions were usually mild to moderate in intensity. In all controlled studies, the discontinuation rate due to adverse events was 12 % for patients receiving ALOND and 5 % for patients receiving placebo. The adverse reactions resulting in discontinuation from ALOND treatment groups were dizziness and somnolence.

Tabulated list of adverse reactions

Selected adverse drug reactions that were treatment related in the pooled analysis of clinical trials are listed in the table below by System Organ Class (SOC). The frequency of these terms has been based on all-causality adverse drug reactions in the clinical trial data set: 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 Frequency not known as the frequency cannot be estimated from the available data.

The adverse reactions listed may also be associated with the underlying disease and concomitant medicines.

Adverse reactions from clinical trials

MedDRA System Organ Class	Frequency	Adverse reactions
Infections and infestations	Common	Nasopharyngitis
Blood and lymphatic system disorders	Uncommon	Neutropenia
Metabolism and nutrition disorders	Common	Increased appetite
	Uncommon	Anorexia, hypoglycaemia
Psychiatric disorders	Common	Euphoric mood, confusion, libido decreased, irritability, depression, disorientation, insomnia
	Uncommon	Depersonalisation, anorgasmia, restlessness, agitation, mood swings, depressed mood, elevated mood, word finding difficulty, hallucination, abnormal dreams, increased libido
	Rare	Panic attack, disinhibition, apathy, suicidal behaviour, suicidal ideation
Nervous system disorders	Very common	Dizziness, somnolence

	Common	Ataxia, disturbance in attention, abnormal coordination, amnesia, memory impairment, tremor, dysarthria, paraesthesia, hypoaesthesia, sedation, balance disorder, lethargy
	Uncommon	Cognitive disorder, nystagmus, speech disorder, myoclonus, hyporeflexia, dyskinesia, psychomotor hyperactivity, postural dizziness, hyperaesthesia, burning sensation, intention tremor, syncope
	Rare	Stupor, hypokinesia, parosmia, ageusia, dysgraphia
Eye disorders	Common	Blurred vision blurred, diplopia
	Uncommon	Peripheral vision loss, visual disturbance, dry eye, eye swelling, visual field defect, reduced visual acuity, eye pain, asthenopia, photopsia, increased lacrimation, eye irritation
	Rare	Mydriasis, oscillopsia, altered visual depth perception, strabismus, visual brightness
Ear and labyrinth disorders	Common	Vertigo
	Uncommon	Hyperacusis
Cardiac disorders	Uncommon	Tachycardia, atrioventricular block first degree, sinus bradycardia
	Rare	Sinus tachycardia, sinus dysrhythmia
Vascular disorders	Uncommon	Hypotension, hypertension, flushing, hot flushes, peripheral coldness
Respiratory, thoracic and mediastinal disorders	Uncommon	Dyspnoea, epistaxis, cough, nasal congestion, rhinitis, snoring
	Rare	Throat tightness, nasal dryness
	Not known	Respiratory depression

Gastrointestinal disorders	Common	Dry mouth, constipation, vomiting, flatulence, abdominal distension
	Uncommon	Salivary hypersecretion, gastroesophageal reflux disease, oral hypoaesthesia
	Rare	Ascites, dysphagia, pancreatitis
Skin and subcutaneous tissue disorders	Uncommon	Sweating, rash papular, urticaria
	Rare	Cold sweat
Musculoskeletal and connective tissue disorders	Common	Muscle cramp, arthralgia, back pain, pain in limb, cervical spasm
	Uncommon	Muscle twitching, joint swelling, myalgia, neck pain, muscle stiffness
	Rare	Rhabdomyolysis
Renal and urinary disorders	Uncommon	Dysuria, urinary incontinence
	Rare	Oliguria, renal failure
Reproductive system and breast disorders	Uncommon	Erectile dysfunction, delayed ejaculation, sexual dysfunction, dysmenorrhoea
	Rare	Amenorrhoea, breast pain, breast discharge, breast enlargement
General disorders and administration site conditions	Common	Fatigue, oedema peripheral, fall, feeling drunk, feeling abnormal, oedema, abnormal gait
	Uncommon	Generalised oedema, asthenia, thirst, chest tightness, pain, pyrexia, chills
Investigations	Common	Increased weight
	Uncommon	Increased alanine aminotransferase, increased blood creatine phosphokinase, increased aspartate aminotransferase, increased blood glucose, decreased platelet count, decreased blood potassium, decreased weight

	Rare	Increased blood creatinine, decreased white blood cell count

Other special populations

Elderly (over 65 years of age)

In a total of 998 elderly patients, no overall differences in safety were observed compared with patients less than 65 years of age.

Post-marketing (see section 4.4)

MedDRA System Organ Class	Adverse reactions
Immune system disorders	Angioedema, allergic reaction, hypersensitivity
Psychiatric disorders	Drug dependence
Nervous system disorders	Headache, loss of consciousness, mental impairment, reversible paralysis
Eye disorders	Keratitis
Cardiac disorders	Congestive heart failure
Respiratory, thoracic and mediastinal disorders	Pulmonary oedema
Gastrointestinal disorders	Swollen tongue, diarrhoea, nausea
Skin and subcutaneous tissue disorders	Face swelling, pruritus, toxic epidermal necrolysis, Stevens-Johnson syndrome
Renal and urinary disorders	Urinary retention
Reproductive system and breast disorders	Gynaecomastia
General disorders and administration site conditions	Malaise

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

4.9 Overdose

In overdoses up to 15 g, no unexpected adverse reactions were reported.

In post-marketing experience, the most commonly reported adverse events observed when ALOND was taken in overdose included affective disorder, somnolence, confusional state, depression, agitation and restlessness. Seizures were also reported.

In rare occasions, cases of coma have been reported.

Treatment of ALOND overdose should include general supportive measures and may include haemodialysis if necessary (see section 4.2 – *Patients with renal impairment*).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 2.5 Anticonvulsants, including anti-epileptics

The active substance, pregabalin, is a gamma-aminobutyric acid (GABA) analogue ((S)-3-(aminomethyl)-5-methylhexanoic acid).

Mechanism of action

In vitro studies show that pregabalin binds to an auxiliary subunit (α_2-δ protein) of voltage-gated calcium channels in the central nervous system, potently displacing [^{3}H]-gabapentin. Two lines of evidence indicate that binding of pregabalin to the α_2-δ site is required for analgesic activity in animal models: (1) Studies with the inactive R-enantiomer and other structural derivatives of pregabalin and (2) Studies of pregabalin in mutant mice with defective medicine binding to the α_2-δ protein. In addition, pregabalin reduces the release of several neurotransmitters, including glutamate, noradrenaline, and substance P. The significance of these effects for the clinical pharmacology of pregabalin is not known.

Pregabalin does not interact with either $GABA_A$ or $GABA_B$ receptors; it is not converted metabolically into GABA or a GABA agonist; it is not an inhibitor of GABA uptake or degradation.

Pregabalin prevents pain-related behaviours in animal models of neuropathic and post-surgical pain, including hyperalgesia and allodynia.

Clinical experience

Neuropathic pain

The effectiveness of pregabalin for the management of neuropathic pain was investigated in 10 double-blind, placebo-controlled, multicentre studies with either twice a day (BD) or three times a day (TDS) dosing. A total of 2 099 patients were enrolled in the 10 studies. To enter the study, patients had to have moderate to severe pain caused by diabetic peripheral neuropathy or pain due to post-Herpes zoster infection.

5.2 Pharmacokinetic properties

Pregabalin steady-state pharmacokinetics is similar in healthy volunteers and patients with chronic pain.

Absorption

Pregabalin is absorbed when administered in the fasted state, with peak plasma concentrations occurring within 1 hour following both single and multiple dose administration. Pregabalin oral bioavailability is estimated to be ≥ 90 % and is independent of dose. Following repeated administration, steady state is achieved within 24 to 48 hours. The rate of pregabalin absorption is decreased when given with food resulting in a decrease in C_{max} by approximately 25 – 30 % and a delay in T_{max} to approximately 2,5 hours. However, administration of pregabalin with food has no clinically significant effect on the extent of pregabalin absorption.

Distribution

In pre-clinical studies, pregabalin has been shown to readily cross the blood brain barrier in mice, rats, and monkeys. Pregabalin has been shown to cross the placenta in rats and is present in the milk of lactating rats. In humans, the apparent volume of distribution of pregabalin following oral administration is approximately 0,56 L/kg. Pregabalin is not bound to plasma proteins.

Biotransformation

Pregabalin undergoes negligible metabolism in humans. Following a dose of radio-labelled pregabalin, approximately 98 % of the radioactivity recovered in the urine was unchanged pregabalin. The N-methylated derivative of pregabalin, the major metabolite of pregabalin found in urine, accounted for 0,9 % of the dose. In pre-clinical studies, there was no indication of racemisation of pregabalin S-enantiomer to the R-enantiomer.

Elimination

Pregabalin is eliminated from the systemic circulation primarily by renal excretion as unchanged

medicine. Pregabalin mean elimination half-life is 6,3 hours. Pregabalin plasma clearance and renal clearance are directly proportional to creatinine clearance (see *Pharmacokinetics in special populations – Renal impairment*). Dosage adjustment in patients with reduced renal function or undergoing haemodialysis is necessary (see section 4.2, Table 1).

Linearity/non-linearity

Pregabalin pharmacokinetics is linear over the recommended daily dose range. Inter-subject pharmacokinetic variability for pregabalin is low (< 20 %). Multiple dose pharmacokinetics is predictable from single-dose data. Therefore, there is no need for routine monitoring of plasma concentrations of pregabalin.

Pharmacokinetics in special populations

Gender

Clinical trials indicate that gender does not have a clinically significant influence on the plasma concentrations of pregabalin.

Renal impairment

Pregabalin clearance is directly proportional to creatinine clearance. In addition, pregabalin is effectively removed from plasma by haemodialysis (following a 4-hour haemodialysis treatment, plasma pregabalin concentrations are reduced by approximately 50 %). Because renal elimination is the major elimination pathway, dosage reduction in patients with renal impairment and dosage supplementation following haemodialysis is necessary (see section 4.2, Table 1).

Hepatic impairment

No specific pharmacokinetic studies were carried out in patients with impaired liver function. Since pregabalin does not undergo significant metabolism and is excreted predominantly as unchanged medicine in the urine, impaired liver function would not be expected to significantly alter pregabalin plasma concentrations.

Elderly (over 65 years of age)

Pregabalin clearance tends to decrease with increasing age. This decrease in pregabalin oral clearance is consistent with decreases in creatinine clearance associated with increasing age. Reduction of pregabalin dose may be required in patients who have age related compromised renal function (see section 4.2, Table 1).

Breastfeeding mothers

The pharmacokinetics of 150 mg pregabalin given every 12 hours (300 mg daily dose) was evaluated in 10 lactating women who were at least 12 weeks postpartum. Lactation had little to no influence on pregabalin pharmacokinetics. Pregabalin was excreted into breast milk with average steady-state concentrations approximately 76 % of those in maternal plasma. The estimated average daily infant dose of pregabalin from breast milk (assuming mean milk consumption of 150 mL/kg/day) was 0,31 mg/kg/day, which on a mg/kg basis would be approximately 7 % of the maternal dose.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule content

Lactose monohydrate

Maize starch

Talc

Capsule shell

Colloidal anhydrous silica

Gelatine

Red iron oxide (75 mg)

Sodium laurilsulfate

Titanium dioxide

Water

Black imprinting ink

Black iron oxide

Potassium hydroxide

Propylene glycol

Shellac

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at or below 25 °C.

6.5 Nature and contents of container

Clear PVC/aluminium blisters containing 14, 56 or 100 hard capsules.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

Viatris South Africa (Pty) Ltd

4 Brewery Street

Isando

Gauteng, 1609

Manufacturer: Pfizer Manufacturing Deutschland GmbH, Freiburg, Germany

8 REGISTRATION NUMBERS

ALOND 25 mg: 45/2.5/0833

ALOND 75 mg: 45/2.5/0834

ALOND 150 mg: 45/2.5/0835

9 DATE OF FIRST AUTHORISATION/ RENEWAL OF AUTHORISATION

21 February 2020

10 DATE OF REVISION OF THE TEXT

29 July 2025