SCHEDULING STATUS: S5

1. NAME OF THE MEDICINE

XANOR® 0,25 mg tablets

XANOR® 0,5 mg tablets

XANOR® 1,0 mg tablets

XANOR® 2,0 mg tablets

XANOR® SR 0,5 mg tablets

XANOR® SR 1,0 mg tablets

XANOR® SR 2,0 mg tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each XANOR 0,25 mg tablet contains 0,25 mg alprazolam and 0,1125 mg sodium benzoate (preservative).

Each XANOR 0,5 mg tablet contains 0,5 mg alprazolam and 0,1125 mg sodium benzoate (preservative).

Each XANOR 1,0 mg tablet contains 1,0 mg alprazolam and 0,1125 mg sodium benzoate (preservative).

Each XANOR 2,0 mg tablet contains 2,0 mg alprazolam and 0,225 mg sodium benzoate (preservative).

Each XANOR SR tablet contains 0,5 mg, 1,0 mg or 2,0 mg alprazolam.

Contains sugar (lactose monohydrate).

Each XANOR 0,25 mg, 0,5 mg and 1,0 mg tablet contains 96,0 mg lactose monohydrate.

Each XANOR 2,0 mg tablet contains 192,0 mg lactose monohydrate.

Each XANOR SR 0,5 mg, 1,0 mg or 2,0 mg tablet contains 221,7 mg lactose monohydrate.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets

XANOR 0,25 mg tablets are white, ovoid shaped, embossed with "Upjohn 29" on the one side and scored on the other side.

XANOR 0,5 mg tablets are pink, ovoid shaped, embossed with "Upjohn 55" on the one side and scored on the other side.

XANOR 1,0 mg tablets are lavender, ovoid shaped, embossed with "Upjohn 90" on the one side and scored on the other side.

XANOR 2,0 mg tablets are white capsule shaped, three scored tablets, embossed with "U94".

XANOR SR 0,5 mg tablets are round, blue, convex tablets with "P&U 57" on one side.

XANOR SR 1,0 mg tablets are round, white, convex tablets with "P&U 59" on one side.

XANOR SR 2,0 mg tablets are pentagonal, blue tablets with "P&U 66"on one side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

XANOR is indicated for the treatment of:

- SHORT-TERM RELIEF OF SYMPTOMS OF ANXIETY
- TREATMENT OF ANXIETY DISORDERS

Anxiety disorder is a condition corresponding most closely to the latest APA Diagnostic and Statistical Manual (DSM) diagnosis of generalised anxiety disorder.

Anxiety or tension associated with the stress of everyday life usually does not require treatment with an anxiolytic.

Diagnostic criteria for generalised anxiety disorder:

A. Generalised, persistent anxiety is manifested by symptoms from three of the following four categories:

1. Motor tension:

Shakiness, jitteriness, jumpiness, trembling, muscle aches, tension, eyelid twitch, inability to relax, furrowed brow, strained face, restlessness and easily startled.

2. Autonomic hyperactivity:

Heart pounding or racing, sweating, cold clammy hands, dry mouth, light-headedness, dizziness,

paraesthesias, upset stomach, diarrhoea, discomfort in the pit of the stomach, hot or cold spells, lump in the throat, flushing, pallor, high resting pulse and respiration rate.

3. Apprehensive expectation:

Fear, anxiety, worry, rumination, and anticipation of misfortune to self and others.

4. Vigilance and scanning:

Hyper attentiveness resulting in distractibility, difficulty in concentrating, insomnia, feeling "on edge", impatience and irritability.

B. The anxious mood has been continuous for at least one month.

C. Not due to another mental disorder, such as depressive disorder or schizophrenia.

D. At least 18 years of age.

- ANXIETY ASSOCIATED WITH DEPRESSION
- MIXED ANXIETY-DEPRESSION
- DEPRESSION

Depression can be variously described as neurotic depression, reactive depression, major depressive disorder, etc, depending upon local psychiatric nosology. Usage has not been established in depression with psychiatric features, in bipolar disorders or in "endogenous" depression (i.e. severely depressed inpatients).

- PANIC DISORDERS

This includes panic disorder with or without agoraphobia. The essential feature of panic disorder is the unexpected panic attack, a sudden onset of intense apprehension, fear, or terror.

Panic disorder is an illness characterised by recurrent panic attacks. Later in the course of this disturbance, certain issues e.g. driving a car or being in a crowded place, may become associated with having a panic attack. These panic attacks are not triggered by situations in which the person is the focus of others' attention (as in social phobia).

Diagnostic criteria for panic disorder:

A. At least three panic attacks within a three-week period in circumstances other than during marked exertion or in a life-threatening situation. The attacks are not precipitated by exposure to a circumscribed phobic stimulus.

B. Panic attacks are manifested by discrete periods of apprehension or fear, and at least four of the following symptoms appear during each attack: dyspnoea, palpitations, chest pain or discomfort, choking or smothering sensations, dizziness, vertigo or unsteady feelings, feelings of unreality, paraesthesias (tingling in hands or feet), hot and cold flushes, sweating, faintness, trembling or shaking, smothering sensations, dizziness.

XANOR is indicated:

- For use of up to six months duration for anxiety and depression and
- For up to eight months in the treatment of panic disorder with or without some phobic avoidance.

The effectiveness for long-term use, exceeding six months has not been established.

4.2 Posology and method of administration

Patients should be periodically re-assessed, and dosage adjustments made, as appropriate.

The optimum dose of XANOR tablets should be individualised based upon the severity of the symptoms and individual patient response. In patients who require higher doses, dosage should be increased cautiously to avoid adverse effects.

When higher dosage is required, the evening dose should be increased before the daytime dose. In general, patients who have not previously received psychotropic medications will require somewhat lower doses than those previously treated with minor tranquillisers, antidepressants or hypnotics or those with a history of chronic alcoholism.

Posology

XANOR tablets	**Usual starting dose***	**Usual dose range**
Anxiety	0,25 to 0,5 mg given 3 times daily	0,5 to 4,0 mg daily, given in divided doses
Mixed anxiety/ depression Anxiety associated with depression	0,5 mg given 3 times daily	1,5 to 4,5 mg daily, given in divided doses
Panic disorders	0,5 – 1,0 mg given at	The dose should be adjusted to patient

	bedtime or 0,5 mg three times daily	response. Dosage adjustments should be in increments no greater than 1 mg every three to four days. With XANOR tablets, additional doses can be added until a three times daily or four times daily schedule is achieved. The mean dose in a large multi-clinic study was 5,7 ± 2,27 mg with occasional patients requiring a maximum of 10 mg daily.
Geriatric patients or in the presence of debilitating disease	0,25 mg given two or three times daily	0,25 to 0,75 mg daily, given in divided doses; to be gradually increased if needed and tolerated
Anxiety	1 mg daily, in one or two doses	0,5 to 4,0 mg daily, in one or two doses
Mixed anxiety/ depression Anxiety associated with depression	1 mg daily, in one or two doses	0,5 to 4,5 mg daily, in one or two doses
Panic disorders	0,5 – 1,0 mg given at bedtime or 0,5 mg two times daily	In clinical trials the mean maintenance dose was between 5 and 6 mg per day given as a single daily dose or divided into two doses daily, with occasional patients needing up to 10 mg per day. The dose should be adjusted to patient response, with dose increments of no greater than 1 mg in the daily dose every three to four days
Geriatrics patients	0,5 to 1,0 mg daily, given in one or two doses	0,5 to 1 mg daily; may be gradually increased if needed and tolerated

* If side effects occur, the dose should be decreased (see section 4.4).

To discontinue treatment in patients taking XANOR tablets, the dosage should be reduced slowly in keeping with good medical practice. It is suggested that the daily dosage of XANOR be decreased by no more than 0,5 mg every three days. Some patients may require an even slower dosage reduction (see section 4.4).

Special populations

It is recommended that the general principle of using the lowest effective dose be followed in elderly or debilitated patients to preclude the development of ataxia or over sedation.

In elderly patients, in patients with advanced liver disease or in patients with debilitating disease, the usual starting dose of XANOR is 0,25 mg, given two or three times daily, and of XANOR SR is 0,5 mg once daily. This may be gradually increased if needed and tolerated. The elderly may be especially sensitive to the effects of benzodiazepines. If side effects occur at the recommended starting dose, the dose may be lowered.

Paediatric population

The safety and efficacy of XANOR has not been established in children under the age of 18 years.

Method of administration

XANOR SR tablets may be administered once daily, preferably in the morning.

The XANOR SR tablets should be taken intact; they should not be chewed, crushed or broken.

4.3 Contraindications

- XANOR is contraindicated in patients with known hypersensitivity to benzodiazepines, alprazolam, or to any component of these formulations.
- XANOR is not recommended for patients whose primary diagnosis is schizophrenia.
- Concomitant administration with antiretroviral protease inhibitors, ketoconazole and itraconazole, as the elimination of XANOR is delayed several fold.
- The safety and efficacy of XANOR has not been established in children below the age of 18 years.
- Benzodiazepines are also contraindicated in patients with myasthenia gravis, severe respiratory insufficiency, sleep apnoea syndrome and severe hepatic insufficiency.

4.4 Special warnings and precautions for use

XANOR usage has not been established in certain types of depression (see section 4.1).

Particular caution should be exercised with the elderly and debilitated who are at particular risk of over-sedation, respiratory depression and ataxia. (The initial oral dosage should be reduced in these patients).

XANOR must be used with caution in patients with:

- Impaired renal function.
- Mild to moderate hepatic insufficiency.
- Pulmonary disease or limited pulmonary reserve.
- Patients suffering from anxiety accompanied by an underlying depressive disorder.
- Patients receiving barbiturates or other central nervous system depressants. There is an additive risk of central nervous system depression when these medicines are taken together.

There have been rare reports of death in patients with severe pulmonary disease shortly after the initiation of treatment with XANOR. A decreased systemic alprazolam elimination rate (e.g. increased plasma half-life) has been observed in both alcoholic liver disease patients and obese patients receiving XANOR.

XANOR produces additive CNS depressant effects when co-administered with alcohol or other medicines producing CNS depression.

Habituation and emotional/physical dependence may occur with XANOR. The risk of dependence increases with higher doses and long-term use and is further increased in patients with a history of alcoholism or drug abuse. Caution should be particularly used when prescribing XANOR to patients who are prone to abuse drugs (e.g. alcoholics and drug addicts) because of their predisposition to habituation and dependence.

Withdrawal symptoms have occurred following rapid decrease or abrupt discontinuance of XANOR. These can range from mild dysphoria and insomnia to a major syndrome which may include abdominal and muscle cramps, vomiting, sweating, tremor, and convulsions. In addition, withdrawal seizures have occurred upon rapid decrease or abrupt discontinuation of therapy with XANOR, and special care must

be taken in the treatment of epileptic patients. See section 4.2 for dose reduction during withdrawal period.

XANOR should be avoided in psychotic patients and patients suffering from mental depression unless there is a marked component of anxiety in their illness.

Suicide

As with other psychotropic medicines, the usual precautions with respect to administration of the medicine and size of the prescription are indicated for severely depressed patients or those in whom there is reason to expect concealed suicidal ideation or plans. Panic disorder has been associated with primary and secondary major depressive disorders and increased reports of suicide among untreated patients.

Mania

Episodes of hypomania and mania have been reported in association with the use of XANOR in patients with depression.

Risk from concomitant use of opioids

Concomitant use of XANOR and opioids may result in sedation, respiratory depression, coma and death. Because of these risks, concomitant prescribing of sedative medicines such as benzodiazepines or related medicines such as XANOR with opioids should be reserved for patients for whom alternative treatment options are not possible.

If a decision is made to prescribe XANOR concomitantly with opioids, the lowest effective dose should be used, and the duration of treatment should be as short as possible (see also general dose recommendation in section 4.2).

The patients should be followed closely for signs and symptoms of respiratory depression and sedation. In this respect, it is strongly recommended to inform patients and their environment to be aware of these symptoms (see section 4.5).

Amnesia

Benzodiazepines may induce anterograde amnesia. The condition occurs most often several hours after ingesting the product and therefore to reduce the risk patients should ensure that they will be able to have uninterrupted sleep of 7 – 8 hours.

Tolerance

Some loss of efficacy to the hypnotic effects of benzodiazepines may develop after repeated use for a few weeks.

Excipients with known effect information

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

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

4.5 Interaction with other medicines and other forms of interaction

The steady state plasma concentrations of imipramine and desipramine have been reported to be increased an average of 31 and 20 %, respectively, by the concomitant administration of XANOR tablets in doses up to 4 mg/day. The clinical significance of these changes is unknown.

Opioids

The concomitant use of sedative medicines such as benzodiazepines or related medicines such as XANOR with opioids increases the risk of sedation, respiratory depression, coma and death because of additive central nervous system (CNS) depressant effect. The dosage and duration of concomitant use should be limited (see section 4.4). Concomitant intake with alcohol is not recommended. XANOR should be used with caution when combined with CNS depressants.

Enhancement of the central depressive effect may occur in cases of concomitant use with antipsychotics (neuroleptics), hypnotics, anxiolytics/sedatives, antidepressant medicines, narcotic analgesics, anti-epileptic medicines, anaesthetics and sedative antihistamines. In the case of narcotic analgesics, enhancement of the euphoria may also occur leading to an increase in psychic dependence.

Pharmacokinetic interactions can occur when XANOR is administered along with medicines that interfere with its metabolism.

CYP3A inhibitors

Pharmacokinetic interactions can occur when XANOR is administered along with medicines that interfere with its metabolism. Compounds which inhibit certain hepatic enzymes (particularly cytochrome P450 3A4) may increase the concentration of XANOR and enhance its activity. Data from clinical and *in vitro* studies with XANOR, and clinical studies with medicines metabolised similarly to XANOR provide evidence for varying degrees of interaction and possible interaction with XANOR for a number of medicines. Based on the degree of interaction and the type of data available, the following recommendations are made:

- Caution and consideration of dose reduction is recommended when XANOR is co-administered with nefazodone, fluvoxamine, and cimetidine.
- Caution is recommended when XANOR is co-administered with fluoxetine, oral contraceptives, sertraline, diltiazem, or macrolide antibiotics such as erythromycin and troleandomycin.

CYP3A4 inducers

Since XANOR is metabolised by CYP3A4, inducers of this enzyme may enhance the metabolism of XANOR. Interactions involving HIV protease inhibitors (e.g. ritonavir) and XANOR are complex and time dependent. Short-term, low doses of ritonavir resulted in a large impairment of XANOR clearance, prolonged its elimination half-life and enhanced clinical effects. However, upon extended exposure to ritonavir, CYP3A induction offset this inhibition. This interaction will require a dose-adjustment or discontinuation of XANOR.

Digoxin

Increased digoxin concentrations have been reported when XANOR was given, especially in elderly (> 65 years of age). Patients who receive XANOR and digoxin should therefore be monitored for signs and symptoms related to digoxin toxicity.

4.6 Fertility, pregnancy and lactation

Pregnancy

The safety of XANOR during pregnancy and lactation has not been established. The potential for congenital malformations in children of patients who have received XANOR during pregnancy exists.

XANOR should not be administered during labour. Given during labour, it crosses the placenta and

may cause the floppy-infant syndrome characterised by central respiratory depression, hypothermia and poor sucking.

Breastfeeding

XANOR should not be administered to mothers breastfeeding their infants, since XANOR is excreted in human breast milk.

4.7 Effects on ability to drive and use machines

Patients should be cautioned about using XANOR while operating motor vehicles or other dangerous activities until it is established that they do not become impaired while taking XANOR.

XANOR causes side effects such as somnolence, which may affect the ability to drive and use machines.

4.8 Undesirable effects

The table below contains adverse events categorised as follows utilising the incidence rates: 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).

Undesirable effects associated with XANOR therapy in patients participating in controlled clinical studies were as follows:

MedDRA System Organ Class	**Frequency**	**Undesirable effects**
Metabolism and nutrition disorders	Common	Decreased appetite
Psychiatric disorders	Common	Confusional state, depression, irritability, libido decreased
	Uncommon	Aggression, insomnia, loss of libido, mood disorder, nervousness
	Rare	Hallucinations, agitation, rage
Nervous system disorders	Very common	Sedation, somnolence
	Common	Ataxia, balance impaired, coordination

		abnormal, dizziness, headache, memory impairment, dysarthria, hypersomnia, lethargy
	Uncommon	Amnesia, increased activity, tremor
	Rare	Intellectual impairment, slurred speech
Eye disorders	Common	Vision blurred
	Rare	Increased intraocular pressure
Gastrointestinal disorders	Common	Constipation, nausea, dry mouth
	Uncommon	Diarrhoea, vomiting
Hepatobiliary disorders	Rare	Abnormal liver function
Skin and subcutaneous tissue disorders	Rare	Dermatitis
Musculoskeletal and connective tissue disorders	Uncommon	Muscle twitching, muscle weakness
Renal and urinary disorders	Uncommon	Enuresis, urinary frequency
	Rare	Urinary retention
Reproductive system and breast disorders	Uncommon	Menstrual irregularities
	Rare	Sexual dysfunction
General disorders and administration site conditions	Common	Fatigue
Investigations	Uncommon	Jaundice, weight decreased, weight increased

Post-marketing surveillance

The following post-marketing events have been reported with XANOR:

MedDRA System Organ Class	**Frequency**	**Undesirable effects**
Endocrine disorders	Less frequent	Hyperprolactinaemia
Psychiatric disorders	Less frequent	Hypomania, mania (see section 4.4), hallucination, anger, aggression, hostility, agitation, libido disorder, abnormal thinking, psychomotor hyperactivity

Nervous system disorders	Less frequent	Dystonia, autonomic nervous system imbalance
Gastrointestinal disorders	Less frequent	Gastrointestinal disorder
Hepatobiliary disorders	Less frequent	Hepatitis, abnormal hepatic function, jaundice
Skin and subcutaneous tissue disorders	Less frequent	Dermatitis, angioedema
Renal and urinary disorders	Less frequent	Incontinence, urinary retention
Reproductive system and breast disorders	Less frequent	Sexual dysfunction, irregular menstruation
General disorders and administration site conditions	Less frequent	Peripheral oedema
Investigations	Less frequent	Increased intraocular pressure

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 asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

Symptoms of overdose with XANOR are extensions of its pharmacological action and include drowsiness, slurred speech, motor incoordination, coma and respiratory depression. Serious sequelae are rare unless other medicines and/or ethanol are concomitantly ingested. Treatment of overdosage is primarily supportive of respiratory and cardiovascular function. The value of dialysis has not been determined. Flumazenil may be used as an adjunct to the management of respiratory and cardiovascular function associated with overdose.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 2.6 Tranquillisers

Alprazolam is an anxiolytic medicine of the benzodiazepine group. Benzodiazepines, including alprazolam, are thought to bind to central nervous system benzodiazepine receptors, thereby increasing the affinity of the receptor for gamma-aminobutyric acid (GABA). GABA, an inhibitory neurotransmitter, modulates the activity of other neurotransmitter systems, including the noradrenergic system.

5.2 Pharmacokinetic properties

Absorption

Alprazolam is almost completely bioavailable following oral administration. The bioavailability and pharmacokinetic characteristics of XANOR tablets or XANOR SR tablets are comparable, except for a slower rate of absorption of alprazolam from XANOR SR tablets. The slower absorption rate for XANOR SR tablets results in peak plasma alprazolam concentrations that are approximately one-half that of an equivalent dose of XANOR tablets; peak concentrations occur within one to two hours after a single dose of XANOR tablets, and 5 to 11 hours after a single dose of XANOR SR tablets. The plasma elimination half-life of alprazolam has been found to be about 11 to 15 hours in healthy adults. A comparable elimination half-life for XANOR SR tablets indicates that the metabolism and elimination of alprazolam are the same for both dosage forms.

Steady-state plasma concentrations are achieved within three to four days of continuous dosing with either dosage form. When equivalent daily doses are given, steady-state peak and trough plasma alprazolam concentrations for XANOR SR tablets given once or twice a day are comparable to XANOR tablets given three or four times a day.

Distribution

In vitro, alprazolam is bound (80 %) to human serum protein.

Biotransformation

The predominant metabolites are alpha-hydroxy-alprazolam, 4-hydroxy alprazolam, and a benzophenone derived from alprazolam. Although they possess some pharmacological activity, the plasma levels of these metabolites are extremely low during chronic dosing.

Elimination

Alprazolam and its metabolites are excreted primarily in the urine.

Linearity/non-linearity

The pharmacokinetics of alprazolam are linear over the recommended dosage range, with plasma concentrations being proportional to dose given.

Special populations

Alprazolam clearance has been reported to be delayed in patients with impaired hepatic and renal function, alcoholism, in elderly or obese patients, and by the co-administration of certain medicines.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

XANOR 0,25 mg, 0,5 mg, 1,0 mg and 2,0 mg tablets:

Colloidal silicon dioxide

Docusate sodium with sodium benzoate

Lactose monohydrate

Magnesium stearate

Microcrystalline cellulose

Starch with erythrosine sodium or

FD & C blue as colourants

XANOR SR 0,5 mg, 1,0 mg and 2,0 mg tablets:

Cellulose methylhydroxypropyl

Lactose monohydrate

Magnesium stearate

Silicon colloidal dioxide

FD & C blue as colourant

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

XANOR 0,25 mg, 0,5 mg, 1,0 mg tablets: 36 months

XANOR 2,0 mg tablets: 60 months

XANOR SR 0,5 mg, 1,0 mg, 2,0 mg tablets: 24 months

6.4 Special precautions for storage

XANOR 0,25 mg, 0,5 mg, 1,0 mg, 2,0 mg tablets: Store at or below 30 °C.

XANOR SR 0,5 mg, 1,0 mg, 2,0 mg tablets: Store at or below 25 °C.

Keep tablets packed in bottles tightly closed.

Keep tablets in the carton until use.

Protect from light.

6.5 Nature and contents of container

XANOR 0,25 mg and 1,0 mg are packed in blister packs of 30 and 100 tablets.

XANOR 0,5 mg is packed in blister packs of 30 and 100 tablets and in bottles containing 500 tablets.

XANOR 2,0 mg is packed in bottles containing 30 and 100 tablets.

XANOR SR tablets are packed in foil blisters of 60 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATES OF REGISTRATION

Viatris Healthcare (Pty) Ltd

4 Brewery Street

Isando

Gauteng, 1609

Tel.: +27(011) 451 1300 / +27(071) 281 2503 (24 hours)

Manufacturer: Sanico N.V., Turnhout, Belgium

8. REGISTRATION NUMBERS

XANOR 0,25 mg tablets: M/2.6/233

XANOR 0,5 mg tablets: M/2.6/234

XANOR 1,0 mg tablets: M/2.6/235

XANOR 2,0 mg tablets: 27/2.6/0096

XANOR SR 0,5 mg tablets: 29/2.6/0504

XANOR SR 1,0 mg tablets:29/2.6/0505

XANOR SR 2,0 mg tablets: 29/2.6/0506

9. DATE OF FIRST AUTHORISATION

XANOR 0,25 mg, 0,5 mg, 1,0 mg tablets: 23 May 1983

XANOR 2,0 mg tablets: 20 October 1993

XANOR SR 0,5 mg, 1,0 mg, 2,0 mg tablets: 21 June 1996

10. DATE OF REVISION OF THE TEXT

30 June 2021

BOTSWANA: S1C

XANOR 0,25 mg – Reg. no.: B9312185

XANOR 0,5 mg – Reg. no.: B9312190

XANOR 1,0 mg – Reg. no.: B9312195

NAMIBIA: NS3

XANOR 0,25 mg – Reg. no.: 90/2.6/001366

XANOR 0,5 mg – Reg. no.: 90/2.6/001367

XANOR 1,0 mg – Reg. no.: 90/2.6/001368

XANOR 2,0 mg – Reg. no.: 04/2.6/0746

XANOR SR 0,5 mg – Reg. no.: 04/2.6/0747

XANOR SR 1,0 mg – Reg. no.: 04/2.6/0748

XANOR SR 2,0 mg – Reg. no.: 04/2.6/0749