SCHEDULING STATUS

S5

PROPRIETARY NAME AND DOSAGE FORM

REDILANZ 2,5 (film-coated tablets)

REDILANZ 5 (film-coated tablets)

REDILANZ 10 (film-coated tablets)

REDILANZ 15 (film-coated tablets)

REDILANZ ODT 5 (orally disintegrating tablet)

REDILANZ ODT 10 (orally disintegrating tablet)

COMPOSITION

REDILANZ 2,5: Each film-coated tablet contains olanzapine 2,5 mg. Contains lactose (sugar).

REDILANZ 5: Each film-coated tablet contains olanzapine 5,0 mg. Contains lactose (sugar).

REDILANZ 10: Each film-coated tablet contains olanzapine 10,0 mg. Contains lactose (sugar).

REDILANZ 15: Each film-coated tablet contains olanzapine 15,0 mg. Contains lactose (sugar).

The inactive ingredients of **REDILANZ 2,5, REDILANZ 5, REDILANZ 10** and **REDILANZ 15** film-coated tablets are: Crospovidone, hydroxypropyl cellulose, hypromellose, lactose monohydrate, macrogol, magnesium stearate, microcrystalline cellulose, purified water and titanium dioxide.

REDILANZ ODT 5: Each orally disintegrating tablet contains olanzapine 5,0 mg. Contains mannitol.

REDILANZ ODT 10: Each orally disintegrating tablet contains olanzapine 10,0 mg. Contains mannitol.

The inactive ingredients of the **REDILANZ ODT 5** and **10** orally disintegrating tablet range are:

Aspartame, crospovidone, magnesium stearate, mannitol, microcrystalline cellulose, guar gum, purified water, pregelatinised starch, silica (colloidal anhydrous) and sodium lauryl sulphate.

PHARMACOLOGICAL CLASSIFICATION

A 2.6.5 Tranquillisers – miscellaneous structures

PHARMACOLOGICAL ACTION

Pharmacodynamics

Olanzapine is an atypical antipsychotic, antimanic and mood-stabilising agent with affinity for $5HT_{2A/2C}$, $5HT_3$, $5HT_6$, dopamine D_4, D_3, D_1, D_2, cholinergic muscarinic receptors ($m_1 – m_5$), alpha-1 (α_1) adrenergic and histamine H_1 receptors.

Olanzapine has been shown to selectively interact with the mesolimbic system without significantly interacting with the extrapyramidal system.

The antagonism of muscarinic receptors (m_1-m_5) may explain the anticholinergic effects of olanzapine while the antagonism of the histamine H_1 receptors may produce the observed somnolence. The orthostatic effects of olanzapine may be due to the antagonism of the α1 adrenergic receptors.

Pharmacokinetics

Absorption

Olanzapine is well absorbed after oral administration, reaching peak plasma concentrations within 5 to 8 hours. The absorption is not affected by food.

Distribution

The plasma protein binding of olanzapine is about 93 % over the concentration range of about 7 to

about 1000 ng/ml.

Olanzapine is bound predominantly to albumin and α1-acid-glycoprotein.

Biotransformation

Olanzapine is metabolised in the liver by conjugative and oxidative pathways. The major circulating metabolite is the 10-N-glucuronide which does not pass the blood-brain barrier.

Cytochromes P450-CYP1A2 and P450-CYP2D6 contribute to the formation of the N-desmethyl and 2-hydroxymethyl metabolites, neither of which has *in vivo* pharmacological activity.

The predominant pharmacologic activity is from the parent compound.

Elimination

After oral administration the elimination half-life of olanzapine in healthy subjects varies on the basis of age and gender:

	< 65 years	≥ 65 years
Men	29 hours	49 hours
Women	39 hours	55 hours

The mean elimination half-life of olanzapine is about 1,5 times greater in the elderly (≥ 65 years) than in non-elderly subjects (< 65 years) (See **WARNINGS AND SPECIAL PRECAUTIONS**).

Approximately 7,3 % is excreted unchanged in the urine.

Smokers

Plasma clearance of olanzapine is higher in smokers (See **WARNINGS AND SPECIAL PRECAUTIONS)**.

Renal impairment

The pharmacokinetics characteristics of olanzapine are similar in patients with severe renal impairment and normal subjects, indicating that dosage adjustment based upon the degree of renal impairment is not required. In addition, olanzapine is not removed by haemodialysis. The effect of

renal impairment on metabolite elimination has not been studied.

INDICATIONS

REDILANZ and **REDILANZ ODT** are indicated for the management of the manifestations of psychotic disorders.

Effectiveness for more than 6 weeks has not been established in controlled trials.

REDILANZ and **REDILANZ ODT** are also indicated for the treatment of acute episodes of moderate to severe mania and for prevention of recurrence of manic or depressive episodes of bipolar disorder.

CONTRAINDICATIONS

Hypersensitivity to olanzapine or to any components of **REDILANZ** or **REDILANZ ODT** tablets.

Patients with known risk of narrow-angle glaucoma.

Children and adolescents: Safety and effectiveness in patients under 18 years of age have not been established.

Dementia-related psychosis and/or behavioural disturbances in elderly patients (see **WARNINGS AND SPECIAL PRECAUTIONS**).

WARNINGS AND SPECIAL PRECAUTIONS

Warnings

- **Discontinuation of treatment**

  Discontinuation reactions which may consist of a cholinergic syndrome (diaphoresis, diarrhoea, sialorrhoea, nausea, vomiting, anxiety, agitation, insomnia and tremor) may occur, usually within a week of discontinuation of treatment with **REDILANZ** or **REDILANZ ODT**.

Withdrawal should be gradual and tapered.

- **Hyperprolactinaemia: REDILANZ** and **REDILANZ ODT** elevate prolactin levels and a modest elevation persists during chronic administration.

- **Neuroleptic malignant syndrome (NMS):** NMS has occurred infrequently in association with olanzapine NMS is a potentially fatal symptom complex. Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria, rhabdomyolysis and acute renal failure. **REDILANZ** and **REDILANZ ODT** should be discontinued should any of the clinical manifestations of NMS or high fever without additional clinical manifestations of NMS be observed.

- **Seizures: REDILANZ** and **REDILANZ ODT** should be used cautiously in patients who have a history of seizures or who are subject to factors which may lower seizure threshold. Seizures have been reported to occur infrequently in patients treated with olanzapine. In most cases, a history of seizures or risk factor for seizures was reported.

- **Tardive dyskinesia:** Olanzapine is associated with a low incidence of treatment emergent dyskinesia. If signs or symptoms of tardive dyskinesia appear in a patient on **REDILANZ** or **REDILANZ ODT** a dose reduction or discontinuation of treatment with **REDILANZ** or **REDILANZ ODT** should be considered. The risk of tardive dyskinesia increases with long-term exposure and symptoms can temporarily deteriorate or even arise after discontinuation of treatment.

- **Hepatic impairment:** Caution should be exercised in patients with signs and symptoms of hepatic impairment, in patients with pre-existing conditions associated with limited hepatic functional reserve and in patients who are being treated with potentially hepatotoxic medicines. Periodic assessment of transaminases is recommended in patients with significant hepatic disease. A starting dose of 5 mg should be considered for patients with moderate hepatic impairment.

- **Safety experience in dementia-related psychosis in elderly patients:**

  Cerebrovascular accident adverse events (CVAE) including stroke in elderly dementia patients.

  REDILANZ and **REDILANZ ODT** are not approved for the treatment of dementia-related psychosis and/or behavioural disturbances as efficacy has not been established in this particular group (See **CONTRAINDICATIONS**).

  In addition, in placebo controlled studies, a 2-fold increase in the incidence of death in olanzapine-treated patients was reported.

  Risk factors that may predispose this patient population to increased mortality are age ≥ 80 years, dysphagia, sedation, malnutrition and dehydration, pulmonary conditions (e.g. pneumonia, with or without aspiration), or concomitant use of benzodiazepines.

  Cerebrovascular adverse events (e.g. stroke, transient ischaemic attack) including fatalities, were reported, especially in elderly patients with dementia-related psychosis.

  All patients who experienced a cerebrovascular event had pre-existing risk factors known to be associated with an increased risk for a CVAE (e.g. history of previous CVAE or transient ischaemic attack, hypertension, cigarette smoking) and presented with co-current medical conditions and/or concomitant medications having a temporal association with CVAE.

- **Hyperglycaemia and diabetes mellitus:**

  Hyperglycaemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with olanzapine**.** Patients with an established diagnosis of diabetes mellitus who are started on **REDILANZ** or **REDILANZ ODT** should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g. obesity, family history of diabetes), who are starting treatment with **REDILANZ** or **REDILANZ ODT** should be monitored for symptoms of hyperglycaemia including polydipsia, polyuria, polyphagia and weakness. Patients who develop symptoms of hyperglycaemia during treatment with **REDILANZ** or **REDILANZ ODT** should undergo fasting blood glucose testing. In some cases, hyperglycaemia has resolved

when olanzapine was discontinued. However, some patients required continuation of anti-diabetic treatment despite discontinuation of suspect medicine.

- Caution should be exercised in dosing the elderly, especially if there are other factors that might additively influence medicine metabolism and/or pharmacodynamic sensitivity (See **WARNINGS AND SPECIAL PRECAUTIONS).**

Special Precautions

- Improvement in the patient's clinical condition may take several days to weeks. Patients should be closely monitored during this period.
- **Concomitant illnesses:**

  Clinical experience with **REDILANZ** and **REDILANZ ODT** in patients with concomitant illnesses is limited. As **REDILANZ** and **REDILANZ ODT** demonstrated anticholinergic activity *in vitro*, caution is advised in patients with symptomatic prostatic enlargement or paralytic ileus and related conditions.
- **Cardiac disorders:**

  REDILANZ and **REDILANZ ODT** have not been evaluated or used to any appreciable extent in patients with a recent history of myocardial infarction or unstable heart disease because of the risk of orthostatic hypotension with **REDILANZ** or **REDILANZ ODT**, caution should be observed in cardiac patients.
- **Renal and hepatic impairment:**

  See **Pharmacokinetic properties**.
- **Elderly patients:** In clinical study reports, in general, there is no indication of any difference in tolerability of **REDILANZ** and **REDILANZ ODT** in the elderly compared to younger adults. The presence of factors that might decrease pharmacokinetic clearance or increase the pharmacodynamic response **to REDILANZ** and **REDILANZ ODT**, should lead to consideration of a lower starting dose in the elderly.

- As postural hypotension has been observed in elderly patients, it is recommended that blood pressure be measured periodically in patients older than 65 years.

- **Orthostatic hypertension:**

  REDILANZ and **REDILANZ ODT** may cause orthostatic hypotension with dizziness, tachycardia and in some patients syncope, especially at the onset of treatment. Caution is advised.

- **Transaminase elevations:**

  Transient elevations of liver transaminases (ALT, AST) have been observed. Caution should therefore be exercised in patients with elevated ALT and/or AST in patients with signs and symptoms of hepatic impairment, in patients with pre-existing conditions associated with limited hepatic functional reserve and in patients who are being treated with potentially hepatotoxic agents. In the event of elevated ALT and/or AST during treatment follow-up should be organised and dose reduction should be considered. In cases when hepatitis has been diagnosed, **REDILANZ** or **REDILANZ ODT** treatment should be discontinued.

- **Patients with haematological disorders:**

  Caution should be exercised when using **REDILANZ** or **REDILANZ ODT** in patients with
  -low leucocyte and/or neutrophil counts due to any reason.
  -a history of medicine-induced bone marrow depression/toxicity,
  -bone marrow depression caused by concomitant illness, radiation therapy or chemotherapy-hypereosinophilic conditions or with myeloproliferative disease.

- **Smokers**:

  Plasma clearance of olanzapine is higher in smokers.

  The combined effects of age, smoking and gender could lead to substantial pharmacokinetic differences. The clearance in young smoking males, for example, may be 3 times higher than in elderly non-smoking females.

Dosing modification may be necessary in patients who exhibit a combination of factors that may result in slower metabolism of olanzapine.

- **Body temperature regulation:**

  Disruption of the body's ability to reduce core body temperature has been reported with antipsychotic medicines, care is advised if **REDILANZ** or **REDILANZ ODT** is prescribed to patients exposed to conditions which may contribute to an elevation in core body temperature.

- **Dysphagia:**

  Oesophageal dysmotility and aspiration have been associated with antipsychotic medicines. **REDILANZ** and **REDILANZ ODT** should be used with caution in patients at risk for aspiration pneumonia.

- **Suicide:**

  Patients being treated with **REDILANZ** or **REDILANZ ODT** may be at high risk of attempting suicide. Close supervision is advised.

- **REDILANZ** film-coated tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take **REDILANZ** film-coated tablets.

- **REDILANZ ODT** contains aspartame, a source of phenylalanine. Caution is advised in patients with phenylketonuria.

- **REDILANZ ODT** also contains mannitol which has a mild laxative action.

Effects on ability to drive and use machines

REDILANZ and **REDILANZ ODT** may cause somnolence. Patients should be cautioned about operating hazardous machinery including motor vehicles until they are reasonably certain that **REDILANZ or REDILANZ ODT** therapy does not affect them adversely.

INTERACTIONS

Concomitant use of **REDILANZ** or **REDILANZ ODT** with:

Other centrally acting agents - Given the primary CNS effects of olanzapine, caution should be exercised when **REDILANZ** or **REDILANZ ODT** is taken in combination with other centrally acting agents (especially those that can cause CNS depression) and alcohol.

Levodopa - **REDILANZ** and **REDILANZ ODT** exhibit *in vitro* dopamine antagonism and may antagonise the effects of levodopa and dopamine agonists.

Antihypertensive agents - **REDILANZ** and **REDILANZ ODT** may enhance the effects of certain antihypertensive agents because of its potential for inducing hypotension.

Medicines that increase the QT or QTc intervals – Increased QTc interval has been reported. Caution should be exercised when **REDILANZ** or **REDILANZ ODT** is prescribed together with other medicines known to increase the QTc interval, especially in the elderly, in patients with congenital long QT syndrome, congestive heart failure, heart hypertrophy, hypokalaemia or hypomagnesaemia.

Olanzapine has α_1 adrenergic antagonist activity. Caution should be exercised in patients who receive treatment with medicinal products that can lower blood pressure by mechanisms other than α_1 adrenergic antagonism.

Potential for other medicines to affect REDILANZ and **REDILANZ ODT - Antacids -** Single doses of antacid (aluminium, magnesium) or cimetidine do not affect the oral bioavailability of olanzapine. However, the concomitant administration of activated charcoal reduced the oral bioavailability of olanzapine by 50 to 60 % and should therefore be taken at least 2 hours before or after **REDILANZ** or **REDILANZ ODT**.

Fluoxetine in combination with **REDILANZ** or **REDILANZ ODT**, may cause an increase in the maximum concentration of olanzapine and a decrease in olanzapine clearance. The effect of repeat dosages and higher dosages of **REDILANZ** and **REDILANZ ODT** has not been evaluated. Combination therapy is not advised.

Potential interactions affecting **REDILANZ** and **REDILANZ ODT**: Since olanzapine is metabolised by CYP1A2, substances that specifically induce, inhibit or act as a substrate to this isoenzyme may affect the pharmacokinetics of olanzapine as in **REDILANZ** and **REDILANZ ODT**.

Inducers of CYP1A2 - The metabolism of olanzapine may be induced by concomitant smoking or by carbamazepine therapy, causing slightly to moderately lower olanzapine plasma levels. The clinical consequences are likely to be limited but clinical monitoring is recommended and an increase of the **REDILANZ** or **REDILANZ ODT** dose may be considered if necessary.

Inhibitors of CYP1A2 - Known potent inhibitors of CYP1A2 activity may decrease olanzapine clearance. Fluvoxamine, a specific CYP1A2 inhibitor, has been shown to significantly inhibit the metabolism of olanzapine. A lower starting dose of **REDILANZ** or **REDILANZ ODT** should be considered in patients who are using fluvoxamine or any other CYP1A2 inhibitors, such as ciprofloxacin or ketoconazole. A decrease in the dose of **REDILANZ** or **REDILANZ ODT** should be considered if treatment with an inhibitor of CYP1A2 is initiated.

Potential for REDILANZ and REDILANZ ODT to affect other medicines - No inhibition of the metabolism of imipramine/desipramine (P450-CYP2D6 or P450-CYP3A/1A2), warfarin (P450-CYP2C9), theophylline (P450-CYP1A2) or diazepam (P450-CYP3A4 and P450-CYP2C19) was evident.

REDILANZ and **REDILANZ ODT** do not interact when co-administered with lithium or biperiden.

Valproate - Olanzapine has been shown to have little potential to inhibit the glucuronidation of valproate, the major metabolic pathway of valproate. Valproate has also been shown to have little effect on the metabolism of olanzapine *in vitro.*
Concomitant administration of valproate and **REDILANZ** or **REDILANZ ODT,** does not require dosage adjustment of valproate.

PREGNANCY AND LACTATION

The safety of **REDILANZ** and **REDILANZ ODT** during pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE

Psychotic disorders

REDILANZ and **REDILANZ ODT** should be administered on a once-a-day schedule without regard to meals, generally beginning with an initial dose of 5 to 10 mg/day, with a target dose of 10 mg/day to be reached within several days.

To evaluate efficacy and to guard against side-effects, dose increases should not be made before one week of treatment because steady state for olanzapine is only achieved after approximately one week.

The dose range is from 5 to 20 mg per day. Increasing the dose above the recommended routine 10 mg daily dose is advised only after appropriate clinical assessment.

It is recommended that responding patients be continued on **REDILANZ** or **REDILANZ ODT** at the lowest dose needed to maintain remission. Patients should be periodically reassessed to determine the need for maintenance treatment.

Acute mania in bipolar disorder

REDILANZ and **REDILANZ ODT** should be administered on a once-a-day schedule without regard to meals, generally beginning with 10 mg/day. Dosage adjustments within the dose range of 5 mg to 20 mg per day, if indicated, should generally occur at intervals of not less than 24 hours.

Preventing recurrence in bipolar disorder

The recommended starting dose is 10 mg/day. Patients who have been receiving **REDILANZ** or **REDILANZ ODT** for treatment of manic episodes, should be continued at the same dose to prevent recurrence.

An increase to a dose greater than the recommended starting dose, within the range of 5 mg to 20 mg daily, is advised only after appropriate clinical assessment and should generally occur at

intervals of not less than 24 hours.

The safety of doses above 20 mg/day has not been evaluated in clinical trials.

Gradual tapering of the dose is advised when treatment with **REDILANZ** or **REDILANZ ODT** is to be discontinued (see **WARNINGS AND SPECIAL PRECAUTIONS**).

Administration of REDILANZ ODT (orally disintegrating tablets)

REDILANZ ODT should be placed in the mouth where the tablet will rapidly disperse in saliva and can therefore easily be swallowed. Removal of the dispersed tablet from the mouth is difficult.

Care must be taken as the tablets are fragile. The tablets should be taken immediately after removal from the blister.

Alternatively, it can be dispersed in a full glass of water immediately before administration.

A starting dose of 5 mg should be considered for patients with hepatic impairment and may also be considered for the elderly patient.

SIDE-EFFECTS

Blood and lymphatic system disorders

Frequent: Eosinophilia

Frequency unknown: Leucopenia, thrombocytopenia, neutropenia

Immune system disorders

Less frequent: Allergic reactions (anaphylactoid reaction, angioedema, pruritus, urticaria)

Metabolic and nutritional disorders

Frequent: Weight gain, increased appetite, hyperglycaemia, hypertriglyceridaemia

Frequency unknown: Development or exacerbation of diabetes, diabetic ketoacidosis, diabetic coma

Psychiatric disorders

Frequent: Personality disorder

Less frequent: Amnesia, anxiety, euphoria, hostility

Nervous system disorders

Frequent: Somnolence, dizziness, headache, akathisia, parkinsonism, dyskinesia, asthenia, agitation, movement disorder, abnormal gait, tremor, articulation impairment, hypertonia

Less frequent: Nervousness, myoclonus, insomnia, stuttering, extrapyramidal effects (neck rigidity, muscle spasms of face, neck or back), seizures, neuroleptic malignant syndrome, dystonia, tardive dyskinesia, speech disorders.

Eye disorders

Frequent: Amblyopia

Frequency unknown: Blepharitis, corneal lesion

Cardiac disorders

Frequent: Chest pain

Less frequent: Bradycardia, tachycardia, changes in ECG parameters, ventricular tachydysrhythmias

Vascular disorders

Frequent: Orthostatic hypotension, hypotension, peripheral oedema

Frequency unknown: Venous thromboembolism

Respiratory, thoracic and mediastinal disorders

Frequent: Rhinitis, pneumonia

Less frequent: Cough, pharyngitis

Frequency unknown: Respiratory infections

Gastrointestinal disorders

Frequent: Dry mouth, constipation

Less frequent: Abdominal pain, pancreatitis

Hepato-biliary disorders

Frequent: Transient asymptomatic elevations of hepatic transaminases (ALT, AST)

Less frequent : Hepatitis

Skin and subcutaneous tissue disorders

Frequent: Photosensitivity reaction

Less frequent: Rash

Musculoskeletal, connective tissue and bone disorders

Less frequent: Extremity pain (other than joint), joint pain, rhabdomyolysis

Frequency unknown: Back pain

Reproductive system and breast disorders

Less frequent: Premenstrual syndrome, priapism

Renal and urinary tract disorders

Frequency unknown: Urinary incontinence

General disorders and administration site conditions

Less frequent: Fever, intentional injury

Investigations

Frequent: Elevated prolactin levels

Less frequent: High creatine phosphokinase

Frequency unknown: Decreased erythrocyte count, haematocrit, haemoglobin, leucocyte count, lymphocytes, thrombocytes and platelets, increased MCHC, lymphocytes, monocytes and eosinophils, decreased bicarbonate, calcium phosphorous, albumin and total protein, increased chloride, GGT and phosphorous

KNOWN SYMPTOMS OF OVER-DOSAGE AND PARTICULARS OF ITS TREATMENT

Signs and symptoms

Frequent symptoms of **REDILANZ** and **REDILANZ ODT** overdose include tachycardia, agitation/aggressiveness, dysarthria, various extrapyramidal symptoms and reduced level of consciousness ranging from sedation to coma.

Other medically significant sequelae of **REDILANZ** and **REDILANZ ODT** overdose will include delirium, convulsion, possible neuroleptic malignant syndrome, respiratory depression, aspiration, hypertension or hypotension, cardiac dysrhythmias and cardiopulmonary arrest. Fatal outcomes have been reported for acute overdoses as low as 450 mg but survival has also been reported following acute overdose of 1 500 mg.

Treatment

The possibility of multiple medicine involvement should be considered. In case of acute overdosage, establish and maintain an airway and ensure adequate oxygenation and ventilation. Gastric lavage (after intubation, if patient is unconscious) and administration of activated charcoal together with a laxative should be considered. The possibility of obtundation, seizures or dystonic reaction of the head and neck following overdose may create a risk of aspiration with induced emesis. Cardiovascular monitoring should commence immediately and should include continuous electrocardiographic monitoring to detect possible arrhythmias.

There is no specific antidote to **REDILANZ** or **REDILANZ ODT**, therefore appropriate symptomatic and supportive measures should be initiated. Hypotension and circulatory collapse should be

treated with appropriate measures, such as intravenous fluids and/or sympathomimetic agents. Induction of emesis is not recommended. Do not use epinephrine (adrenaline), dopamine or other sympathomimetics with β-agonist activity, since β-stimulation may worsen hypotension in the setting of **REDILANZ** or **REDILANZ ODT**-induced α-blockade. Close medical supervision and monitoring should continue until the patient recovers.

IDENTIFICATION

REDILANZ 2,5: White, film-coated, oval, biconvex film-coated tablets, debossed 'OLZ' on the one side and '2,5' on the other side.

REDILANZ 5: White, film-coated, oval, biconvex film-coated tablets, debossed 'OLZ' on one side and '5' on the other side.

REDILANZ 10: White, film-coated, oval, biconvex film-coated tablets, debossed 'OLZ' on the one side and '10' on the other side.

REDILANZ 15: White, film-coated, round, biconvex film-coated tablets, debossed 'OLZ' on the one side and '15' on the other side.

REDILANZ ODT 5: Yellow coloured round shaped tablets, convex on one side and flat on the other side. This tablet is 5,0 mm in diameter and has a thickness of 2,2 to 2,8 mm.

REDILANZ ODT 10: Yellow coloured round shaped tablets, convex on one side and flat on the other side. This tablet is 6,4 mm in diameter and has a thickness of 2,8 to 3,4 mm.

PRESENTATION

REDILANZ 2,5: Aluminium / Aluminium blister strips packed into outer cartons of 10, 28 or 30 film-coated tablets

REDILANZ 5: Aluminium / Aluminium blister strips packed into outer cartons of 10, 28 or 30 film-coated tablets

REDILANZ 10: Aluminium / Aluminium blister strips packed into outer cartons of 10, 28 or 30 film-coated tablets

REDILANZ 15: Aluminium / Aluminium blister strips packed into outer cartons of 10, 28 or 30 film-coated tablets

REDILANZ ODT 5: Aluminium / Aluminium blister strips packed into outer cartons of 7, 10, 14 or 30 orally disintegrating tablets

REDILANZ ODT 10: Aluminium / Aluminium blister strips packed into outer cartons of 7, 10, 14 or 30 orally disintegrating tablets

STORAGE INSTRUCTIONS

REDILANZ and **REDILANZ ODT** should at all times be kept out of reach of children as even small doses may be fatal to them.

Store at or below 25 °C. Protect from light and moisture.

Keep blisters in the carton and keep the tablets in the blister until required for use.

REDILANZ 5 and 10 ODT: The orally disintegrating tablets are fragile and must be removed from the blister with care.

KEEP OUT OF THE REACH OF CHILDREN.

REGISTRATION NUMBERS

REDILANZ 2,5: 42/2.6.5/0814

REDILANZ 5: 42/2.6.5/0815

REDILANZ 10: 42/2.6.5/0816

REDILANZ 15: 42/2.6.5/0817

REDILANZ ODT 5: 45/2.6.5/0323

REDILANZ ODT 10: 45/2.6.5/0324

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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