SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

TRITTICO 50 mg
TRITTICO 100 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

TRITTICO 50 mg film-coated tablets
Each film coated tablet of Trittico 50 mg contains: trazodone hydrochloride 50 mg equivalent to trazodone 45.5 mg.
Excipients with known effect: lactose monohydrate, sunset yellow (E 110), castor oil.
TRITTICO 100 mg film-coated tablets
Each film coated tablet of Trittico 100mg contains: trazodone hydrochloride 100 mg equivalent to approximately trazodone 91.1 mg.
Excipients with known effect: lactose monohydrate, castor oil.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film coated tablets.

Trittico 50 mg:
pale orange yellow, smooth, glossy, round, biconvex film-coated tablets with one sided central score line.
The tablets can be divided into two equal halves.

Trittico 100mg:
White to off-white, smooth, glossy, round, biconvex film-coated tablets with one sided central score line.
The tablets can be divided into two equal halves.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of depression, with or without anxiety.

4.2 Posology and method of administration

Posology
The dosage should be determined with caution and treatment initiated with the minimum effective dose. The patient should be reassessed regularly. It is recommended to start treatment with a night-time dose and increasing daily doses. The course of treatment should last at least one month.

TABLETS
The tablets can be split to enable gradual dosing with divided doses, depending on the severity of the disease and the patient's weight, age and general condition.
The tablets cannot be chewed or crushed – as they are film coated.

Adults:
initially 75 - 150 mg daily, administered in repeated doses after meals. The night-time dose must be taken before going to sleep.
The dose may be increased to up to 300 mg daily, to be taken in repeated doses, with the largest part taken at bedtime.
In hospitalised patients, the dose may be increased further, to up to 600 mg daily in repeated doses.

Elderly (from 65 Years of age) and frail patients
The recommended starting dose is 100 mg daily, administered in a single daily dose or divided into several doses. The daily dose may be increased to up to 150 mg daily if well tolerated. Patients should not exceed the maximum dose of 300 mg per day.

Paediatric population
Trittico is contraindicated in children and adolescents (see section 4.3).

Hepatic and renal impairment
Caution should be exercised in the event of hepatic impairment or severe renal impairment (see section 4.4).

Method of administration
Should preferably be taken on a full stomach.
Taking Trittico after meals lowers the chances of side effects.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
Alcohol intoxication and intoxication with hypnotics.
Acute myocardial infarction.
Children and adolescents.

4.4 Special warnings and precautions for use

Trittico is not generic to other medicines containing Trazodone. When switching other medicines containing trazodone to Trittico, patient must be medically monitored.
In clinical trials, suicidal behaviour (suicide attempts and suicidal thoughts) and hostility (predominantly aggressiveness, oppositional behaviour and anger) have been observed more frequently in children and adolescents treated with antidepressants than in those treated with a placebo. Moreover, long-term safety data on children and adolescents regarding growth, maturation and cognitive and behavioural development are not available.

Suicide/suicidal thoughts or clinical worsening
Depression is associated with increased risk of suicidal thoughts, self-harm and suicide (suicide/related events). This risk persists until significant remission occurs. As improvement may not occur during the first few weeks or more of treatment, patients should be closely monitored until such improvement occurs. It is general clinical experience that the risk of suicide may increase in the early stages of recovery.

Patients with a history of suicidal behaviour or thoughts, or those exhibiting a significant degree of suicidal ideation prior to commencement of treatment, are at greater risk of suicidal thoughts or suicide attempts, and should receive careful monitoring during treatment. A meta-analysis of placebo-controlled clinical trials of antidepressant drugs in the treatment of psychiatric disorders showed an increased risk of suicidal behaviour with antidepressants compared to placebo in patients under 25 years old.

Close supervision of patients and in particular those at high risk should always accompany drug therapy with antidepressants, especially in early treatment and following dose changes. Patients (and caregivers of patients) should be alerted of the need to monitor for any clinical worsening, suicidal behaviour or thoughts or unusual changes in behaviour and to seek medical advice immediately if these symptoms appear.

To minimise the potential risk of suicide attempts, particularly at the start of treatment, only restricted quantities of trazodone should be prescribed at each visit.

It is recommended that careful dosing and regular monitoring be adopted in patients with:

- Epilepsy - in particular, abrupt dosage increases or decreases should be avoided
- Hepatic or renal impairment, particularly if severe
- Heart disease, such as angina pectoris, conduction disorders or AV blocks of different degrees, recent myocardial infarction
- Hyperthyroidism
- Micturition disorders, such as prostate hypertrophy, although problems would not be anticipated as the anticholinergic effect of trazodone is negligible
- Acute narrow angle glaucoma, increased intraocular pressure, although major changes have not yet been observed, due to the minor anticholinergic effect of trazodone.

Should jaundice occur in a patient, treatment must be withdrawn. Given the hepatic metabolism and the risk of hepatotoxicity, periodical monitoring of liver functions is recommended (see sections 4.8 and 5.2).

Administration of antidepressants in patients with schizophrenia or other psychotic disorders may result in a possible worsening of psychotic symptoms. Paranoid thoughts may be intensified. During treatment with trazodone, a depressive episode may change from manic depressive psychosis into manic psychosis. If this occurs, trazodone treatment must be discontinued.

Interactions in terms of serotonin syndrome/malignant neuroleptic syndrome have been reported in the event of concomitant use of other serotonergically acting substances (e.g. tricyclic antidepressants, SSRIs, SNRIs and MAO inhibitors) and neuroleptics. Cases of malignant neuroleptic syndrome with fatal outcome have been reported in cases of coadministration with neuroleptics, for which this syndrome is a known possible adverse drug reaction (see sections 4.5 and 4.8 for further information).

Agranulocytosis may present with influenza-like symptoms. Blood tests should therefore be performed if the patient develops a sore throat and fever.

Hypotension, including orthostatic hypotension and syncope, has been reported in patients taking trazodone. Concomitant administration of antihypertensive therapy with trazodone may require a reduction in the dose of the antihypertensive drug.

<u>Elderly (from 65 Years of age)</u>
Elderly patients are often more sensitive to the effects of antidepressants and, in particular, may more often experience orthostatic hypotension, drowsiness and other anticholinergic effects of trazodone.
Careful consideration should be given to the potential additive effects with concomitant treatment use, such as with other psychotropics or antihypertensives, or in the presence of risk factors such as comorbidities, which can exacerbate these reactions.
Patients (and caregivers of patients) should be informed of the potential onset of these reactions and should be monitored closely for such effects at the start of treatment and before and following dose increases.

Following therapy with trazodone, particularly for a prolonged period, an incremental dosage reduction prior to withdrawal is recommended, to minimise the occurrence of withdrawal symptoms, characterised

by nausea, headache, and malaise.

There is no evidence that trazodone possesses any addictive properties.

As with other antidepressants, cases of QT interval prolongation have been reported rarely with trazodone. Special precautions should be taken when administering trazodone with other medicinal products known to prolong the QT interval. Trazodone should be used with caution in patients with cardiovascular disease, including conditions associated with prolongation of the QT interval.

CYP3A4 inhibitors may lead to a significant increase in the plasma concentration of trazodone. See section 4.5 for further information.

As with other drugs with alpha-adrenolytic activity, cases of priapism have been reported rarely during treatment with trazodone. This may be treated with an intracavernosal injection of an alpha-adrenergic agent such as adrenaline or metaraminol. However there are reports of trazodone-induced priapism which have required surgical intervention or led to permanent sexual dysfunction. Patients developing this suspected adverse drug reaction should cease trazodone immediately.

Interference with urine tests
Due to cross-reactivity between a metabolite of trazodone, meta-Chlorophenylpiperazine (m-CPP), and a structurally similar drug, 3,4-methylenedioxymethamphetamine (MDMA, ecstasy), the use of immunoassay drug screening in urine may give a false positive result for amphetamine. In these cases, confirmatory testing is recommended, using techniques based on mass spectrometry (MS).

Important information about some of the excipients

Film-coated tablets
Trittico 50 mg and 100 mg film-coated tablets contain:
- **lactose:** patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicinal product;

- **castor oil:** may cause stomach upset and diarrhoea;
- **sodium:** this medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

Trittico 50 mg film-coated tablets contain sunset yellow (E110)
Sunset yellow (E110): may cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction

General
The sedative effects of antipsychotics, hypnotics, sedatives, anxiolytics, and antihistaminic drugs may be intensified; dosage reduction is recommended in such instances.

The metabolism of antidepressants is accelerated due to the hepatic effects of oral contraceptives, phenytoin, carbamazepine and barbiturates. The metabolism of antidepressants is inhibited by cimetidine and some other antipsychotics.

CYP3A4 inhibitors
In vitro drug metabolism studies suggest that there is a potential for drug interactions when trazodone is coadministered with cytochrome P4503A4 inhibitors (CYP3A4), such as erythromycin, ketoconazole, itraconazole, ritonavir, indinavir and nefazodone. CYP3A4 inhibitors may lead to a significant increase in the plasma concentration of trazodone. It has been confirmed by *in vivo* studies in healthy volunteers, that a

ritonavir dose of 200 mg BID increases the plasma levels of trazodone greater than two-fold, leading to nausea, syncope and hypotension. Therefore, if trazodone is administered with a potent CYP3A4 inhibitor, a reduction in the dose of trazodone is needed. However, coadministration of trazodone and potent CYP3A4 inhibitors should be avoided where possible.

Carbamazepine
Coadministration of carbamazepine and trazodone results in reduced trazodone plasma concentrations. Concomitant use of carbamazepine 400 mg daily led to a decrease in plasma levels of trazodone and its active metabolite m-Chlorophenylpiperazine of 76% and 60%, respectively. For this reason, patients taking trazodone in combination with carbamazepine should be closely monitored to assess whether there is a need for an increased dose of trazodone.

Tricyclic antidepressants
Concomitant use with trazodone should be avoided due to the risk of interaction. Carefully evaluate the possibility of onset of serotonin syndrome and cardiovascular adverse effects.

Fluoxetine
Rare cases have been reported of elevated trazodone plasma levels and adverse effects when trazodone had been combined with fluoxetine, a CYP1A2/2D6 cytochrome inhibitor. The mechanism underlying a pharmacokinetic interaction is not fully understood. A pharmacodynamic interaction (serotonin syndrome) cannot be excluded.

Monoamine oxidase inhibitors (MAOIs)
Possible interactions with monoamine oxidase inhibitors (MAOIs) have occasionally been reported. Although some doctors do give both concurrently, use of trazodone concomitantly with MAOIs, or within two weeks after discontinuation of MAOI treatment, is not recommended. The administration of MAOIs within one week of stopping trazodone treatment is also not recommended.

Phenothiazines
Severe orthostatic hypotension has been observed in the event of concomitant use of phenothiazines, e.g. chlorpromazine, fluphenazine, levomepromazine, and perphenazine.

Anaesthetics and muscle relaxants
Trazodone hydrochloride may enhance the effects of muscle relaxants and volatile anaesthetics, and caution should be exercised in such instances.

Alcohol
Trazodone intensifies the sedative effects of alcohol. Alcohol intake should be avoided during trazodone therapy.

Levodopa
Antidepressants can accelerate the metabolism of levodopa.

Other
Concomitant use of trazodone with drugs known to prolong the QT interval may increase the risk of ventricular arrhythmias, including “torsades de pointes”. Caution should be taken when these drugs are co-administered with trazodone.

Since trazodone is only a weak inhibitor of noradrenaline re-uptake and does not modify the blood pressure response to tyramine, interference with the hypotensive action of guanethidine-like compounds is unlikely. However, studies in laboratory animals suggest that trazodone may inhibit most of the acute actions of clonidine. In the case of other types of antihypertensive drugs, although no clinical interactions have been reported, the possibility of potentiation should be considered.

Undesirable effects may be more frequent during concomitant use of plant-based medicinal preparations containing St John's Wort (*Hypericum perforatum*).

There have been reports of changes in prothrombin time in patients receiving trazodone and warfarin.
Combination of trazodone with digoxin and phenytoin may result in elevated levels of these chemicals in the blood. Monitor plasma concentrations in these patients.

4.6 Fertility, pregnancy and lactation

Pregnancy
Data on a limited number (< 200) of exposed pregnancies indicate that there are no adverse effects of trazodone on pregnancy or on the health of the foetus/newborn. To date, no other relevant epidemiological data are available. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/foetal development, parturition or postnatal development at therapeutic doses (see section 5.3).
Caution should be taken when trazodone is administered to pregnant women. When trazodone is used until delivery, newborns should be monitored for withdrawal syndromes.

Breastfeeding
Limited data indicate that excretion of trazodone in human milk is low, but levels of the active metabolite are not known. Given the lack of data, the decision on the use of trazodone during breastfeeding must be made taking into account the benefits of breastfeeding and the benefits of trazodone therapy for the woman.

4.7 Effects on ability to drive and use machines

Trazodone has minor or moderate influence on the ability to drive and use machines. Patients should be warned of the risks of driving or using machines, unless they are sure they are not affected by drowsiness, sedation, vertigo, confusional state or blurred vision.

4.8 Undesirable effects

Cases of suicidal thoughts and behaviour have been reported during trazodone therapy or soon after discontinuation of treatment.
The following symptoms, some of which are commonly reported in cases of untreated depression, have also been recorded in patients receiving trazodone therapy:

MedDRA system organ class	**FREQUENCY** *not known (cannot be estimated from the available data)*
Blood and lymphatic system disorders	Blood dyscrasias (agranulocytosis, thrombocytopenia, eosinophilia, leukopenia and anaemia)
Immune system disorders	Allergic reactions
Endocrine disorders	Syndrome of Inappropriate Antidiuretic Hormone Secretion
Metabolism and nutrition disorders	Hyponatraemia[1], weight loss, anorexia, increased appetite
Psychiatric disorders	Suicidal ideation or suicidal behaviour[2], confusional state, insomnia, disorientation, mania, anxiety, nervousness, agitation (very occasionally exacerbating to delirium), delirium, aggressive reaction, hallucinations, nightmares, decreased libido, withdrawal syndrome
Nervous system disorders	Serotonin syndrome, convulsions, malignant neuroleptic syndrome, dizziness, vertigo, headache, drowsiness[3], restlessness, decreased alertness, tremor, blurred vision, memory disturbance, myoclonus, expressive aphasia, paraesthesia, dystonia, altered taste.
Cardiac disorders	Cardiac arrhythmias[4] (including torsades de pointes, palpitations, premature ventricular contractions, ventricular couplets, ventricular tachycardia), bradycardia, tachycardia, ECG abnormalities (QT prolongation)
Vascular disorders	Orthostatic hypotension, hypertension, syncope
Respiratory, thoracic and mediastinal disorders	Nasal congestion, dyspnoea
Gastrointestinal disorders	Nausea, vomiting, dry mouth, constipation, diarrhoea, dyspepsia, stomach pain, gastroenteritis, increased salivation, paralytic ileus
Hepatobiliary disorders	Hepatic function abnormalities (including jaundice and hepatocellular damage)[5], intrahepatic cholestasis
Skin and subcutaneous tissue disorders	Skin rash, pruritus, hyperhidrosis
Musculoskeletal and connective tissue disorders	Pain in limbs, back pain, myalgia, arthralgia
Renal and urinary disorders	Micturition disorders
Reproductive system and breast disorders	Priapism[6]
General disorders and administration site conditions	Weakness, oedema, influenza-like symptoms, fatigue, chest pain, fever
Investigations	High liver enzymes

1 Fluid and electrolyte status should be monitored in symptomatic patients.

2 See also section 4.4

3 Trazodone is an antidepressant with sedative properties and drowsiness is sometimes seen in the first few days of treatment, but this generally disappears as therapy continues

4 Studies in animals have shown that trazodone is less cardiotoxic than tricyclic antidepressants, and clinical studies suggest that it is less likely to cause cardiac arrhythmias in humans. Clinical studies in patients with pre-existing heart disease indicate that trazodone can be arrhythmogenic in some patients of that population.

5 Adverse effects on hepatic function, sometimes severe, have been reported rarely.

6 See also section 4.4.

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. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form https://sideeffects.health.gov.il

4.9 Overdose

Features of toxicity
The most frequently reported reactions to overdose include drowsiness, vertigo, nausea and vomiting.
In more serious cases coma, tachycardia, hypotension, hyponatraemia, convulsions and respiratory failure have been reported.
Cardiac features may include bradycardia, QT interval prolongation and "torsades de pointes".
Symptoms may appear within 24 hours or more after overdose.

Overdoses of trazodone in combination with other antidepressants may cause serotonin syndrome.

Treatment
There is no specific antidote to trazodone. Activated charcoal may be used in adults who have ingested more than 1 g of trazodone, or in children who have ingested more than 150 mg of trazodone, within 1 hour of presentation of symptoms. Alternatively, in adults, gastric lavage may be considered within one hour of ingestion of a potentially dangerous overdose.

In the event of overdose, patients must be monitored for at least 6 hours after ingestion (or 12 hours if a prolonged-release preparation has been taken).
Monitor BP, pulse and Glasgow Coma Scale (GCS). Monitor oxygen saturation if GCS is reduced.
Cardiac monitoring is appropriate in symptomatic patients.
Single brief convulsions do not require treatment. Frequent or prolonged convulsions must be controlled with intravenous diazepam (0.1-0.3 mg/kg body weight) or lorazepam (4 mg in adults and 0.05 mg/kg in children).
If these measures do not control the fits, administer an intravenous infusion of phenytoin.
Provide oxygen and correct acid-base and metabolic disturbances as required.

Treatment is symptomatic and supportive in the case of hypotension and excessive sedation. If severe hypotension persists consider use of inotropes, such as dopamine or dobutamine.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: psychoanaleptics, antidepressants
ATC code: N06AX05
Trazodone is a triazolopyridine derivative which is effective in the treatment of all types of depression, including depression associated with anxiety and sleep disorders (ATC code: N06AX05), and is characterised by a short onset of action (approximately one week).
Trazodone is a serotonin re-uptake inhibitor and an antagonist of 5-HT_2 receptors, the activation of which is commonly associated with insomnia, anxiety, psychomotor agitation and sexual function disorders.
Unlike other psychotropic drugs, trazodone is not contraindicated in glaucoma or micturition disorders and it does not have extrapyramidal effects. Additionally, since it does not potentiate adrenergic transmission and is virtually devoid of anticholinergic activity, it does not have the typical effects of tricyclic antidepressants on heart conduction.

5.2 Pharmacokinetic properties

Absorption

After oral administration of Trittico 100 mg as a single dose in young patients, a C_{max} of 1.2 μg/ml is reached with T_{max} at 1 hour. The $AUC_{0-\infty}$ is 7.3 μg/ml/h and the half-life is 6.6 hours.

After oral administration of Trittico 100 mg in a single dose in elderly patients, a C_{max} of 1.6 μg/ml is reached, with a T_{max} of approximately 1.5 hours after receiving the dose and an $AUC_{0-\infty}$ of approximately 17 μg/ml/h. After repeated administration, the T_{max} and AUC remain practically unchanged; the C_{max} is approximately 2 μg/ml. The half-life is 9-11 hours.

Biotransformation

In vitro studies in human liver microsomes show that trazodone is mainly metabolised by cytochrome P450 3A4 (CYP3A4).

5.3 Preclinical safety data

Acute toxicity. The LD_{50} of trazodone by oral administration is 610 mg/kg in mice, 486 mg/kg in rats and 560 mg/kg in rabbits. The effects observed consisted of sedation, salivation, palpebral ptosis and clonic convulsions.

Repeated toxicity. Subchronic studies were carried out in rats, rabbits and dogs and chronic studies in rats, dogs and monkeys. The oral doses administered ranged between 15 and 450 mg/kg/day in rats, 15 and 100 mg/kg/day in rabbits, 3 and 100 mg/kg/day in dogs, and between 20 and 80 mg/kg/day in monkeys. In the rat studies, treatment caused hypertrophy of the hepatocytes and smooth endoplasmic reticulum with consequent hepatomegaly. This effect is the result of a detoxification mechanism that cannot be interpreted as a pathological phenomenon. Furthermore, lethal doses also produced effects already observed in acute toxicity studies. The relevant NOEL (No Observed Adverse Effect Level) was 30 mg/kg/day. In rabbits, only CNS-depressant effects were observed with a relative NOEL of 50 mg/kg/day. In dogs, the symptoms already observed with acute intoxication were worsened with repeated administrations and the relative NOEL was 10 mg/kg/day. Monkeys appeared to be more resistant than dogs, presenting only pharmacodynamic disturbances. The NOEL was 20 mg/kg/day.

Reproductive toxicity. No effects on fertility were observed in rats up to the dose of 300 mg/kg/day. Teratogenicity studies in rats showed an increase in embryolethal effects only at doses that have toxic effects on the maternal organism (300-450 mg/kg/day). In rabbits, embryolethal effects and rare cases of congenital anomalies were observed only at toxic doses in the mothers (150-450 mg/kg/day). The absence of direct effects on the embryo is confirmed by studies of the passage of trazodone through the placental barrier in rats. Concentrations of the drug in the embryonic tissues and amniotic fluid were found to be negligible. Peri- and post-natal studies in rats showed only a reduction in the body weight increase of newborn pups at doses of over 30 mg/kg/day.

Mutagenicity. In vitro mutagenicity tests (in bacterial cells, V77 cells of Chinese hamsters, in murine lymphoma cells, chromosomal aberrations in CHO, CHL/IU cells and human lymphocytes) and in vivo mutagenicity tests (micronucleus test in mice and analysis of the chromosomal metaphase in rats) did not show any mutagenic effects.

Carcinogenic potential. Studies carried out in mice and rats did not reveal any potential risk of tumours.

Antigenicity. Trazodone was found to be devoid of antigenic activity.

Cardiotoxicity. The cardiovascular effects of trazodone were studied in rats, guinea pigs, cats and dogs. The drug showed an almost total lack of cardiotoxicity since no variations in ECG tracings were observed at non hypotensive doses.

Hormonal effects. Single doses of over 20 mg/kg administered intraperitoneally in the female rat caused a mild increase in prolactin. This effect disappeared with chronic administrations in the diet.

Drug dependence. Two studies performed in rats excluded any potential drug-dependence effects.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Trittico 50 mg:
Lactose monohydrate,
Calcium Hydrogen Phosphate* 2 H20,
Microcrystalline cellulose,
Maize starch,
Sodium starch glycolate,type A,
Povidone,
Magnesium stearate,
Ethylcellulose,
Sunset yellow (E 110),
Castor oil,virgin,
E-wax,
Talc.

***Trittico 100 mg*:**
Lactose monohydrate,
Calcium Hydrogen Phosphate* 2 H20,
Microcrystalline cellulose,
Maize starch,
Sodium starch glycolate,type A
Povidone,
Magnesium stearate,
Ethylcellulose,
Talc,
Castor oil,Virgin
E wax.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions, but it is recommended to be stored in room temperature.

6.5 Nature and contents of container

TRITTICO 50 mg: 2 PVC/aluminium blisters, each containing 15 tablets, pack of 30 tablets.
TRITTICO 100 mg: 2 PVC/aluminium blisters, each containing 15 tablets, pack of 30 tablets.

6.6 Special precautions for disposal and other handling

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

7. MARKETING AUTHORIZATION HOLDER & IMPORTER

RAZ Pharmaceutics Ltd.,
31 Gesher haetz st. industrial park, Emek hefer, Israel.

8. MARKETING AUTHORISATION NUMBERS

TRITTICO 50 mg, film-coated tablets, 30 tablets 173-30-36297-00
TRITTICO 100 mg, film-coated tablets, 30 tablets 173-31-36296-00

Revised in **September 2023** according to MOHs guidelines.

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