***Bronchospastic Diseases*:** PATIENTS WITH BRONCHOSPASTIC DISEASES SHOULD, IN GENERAL, NOT RECEIVE BETA BLOCKERS, including metoprolol tartrate . Because of its relative $beta_1$ selectivity, however, Metoprolol tartrate may be used with caution in patients with bronchospastic disease who do not respond to, or cannot tolerate, other antihypertensive treatment. Since beta1 selectivity is not absolute, a $beta_2$-stimulating agent should be administered concomitantly, and the lowest possible dose of Metoprolol tartrate should be used. In these circumstances it would be prudent initially to administer metoprolol tartrate in smaller doses three times daily, instead of larger doses two times daily, to avoid the higher plasma levels associated with the longer dosing interval.

For the use of a Registered Medical Practitioner only

1. GENERIC NAMEAND BRAND NAME

Metoprolol Succinate Extended-Release Tablets I.P. 25 mg
Supermet™ - XL 25

Metoprolol Succinate Extended-Release Tablets I.P. 50mg
Supermet™ - XL 50

Metoprolol Succinate Extended-Release Tablets I.P. 100 mg
Supermet™ XL 100

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Supermet™ XL 25
Each film-coated extended release tablet contains:

Metoprolol Succinate I.P.	23.75 mg
equivalent to Metoprolol Tartrate	25 mg

Colour: Titanium dioxide I.P.

Supermet™ - XL 50
Each film-coated extended release tablet contains:

Metoprolol Succinate I.P.	47.5 mg
equivalent to Metoprolol Tartrate (as extended release)	50 mg
Excipients	q.s.

Colour: Lake Sunset Yellow FCF & Lake Tartrazine

Supermet™ XL 100
Each film-coated extended release tablet contains:

Metoprolol Succinate I.P.	95mg
equivalent to Metoprolol Tartrate	100mg
Excipients	q.s.

Colour: Ferric Oxide (Red) USP - NF

3. DOSAGE FORM AND STRENGTH
Kindly refer to section 1 & 2

4. CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATION

Functional heart disorders,migraine prophylaxis, cardiac arrhythmias, prevention of cardiac death and reinfarction after the acute phase of myocardial infarction, stable symptomatic CHF.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

Administer once daily. In some patients the dosages have to be individualized and titration may be required.

When switching from immediate release metoprolol tablet to metoprolol succinate extended-release tablet, for the treatment of hypertension and angina, the same total daily dose is recommended.

Hypertension

The usual initial dosage is 25 to 100 mg daily in a single dose. The dosage may be increased (up to 400 mg) at weekly (or longer) intervals until optimum blood pressure reduction is achieved. In general, the maximum effect of any given dosage level will be apparent after 1 week of therapy.

Angina Pectoris

The dosage of metoprolol succinate extended-release tablets should be individualized. The usual initial dosage is 100 mg once a day

The dosage may be gradually increased at weekly intervals until optimum clinical response has been obtained or there is a pronounced slowing of the heart rate.. For discontinuation of treatment, the dosage should be reduced gradually over a period of 1 or 2 weeks.

Heart Failure

Dosage must be individualized and closely monitored during up titration. If used, the dosing of diuretics, ACE inhibitors, and digitalis should be stabilized prior to initiation of metoprolol therapy

The recommended starting dose is 25 mg once daily for two weeks in patients with NYHA Class II heart failure and 12.5 mg once daily in patients with more severe heart failure. Every two weeks, the dose should be doubled to the highest dosage level tolerated by the patient.

If transient worsening of heart failure occurs, it may be treated with increased doses of diuretics, and it may also be necessary to lower or temporarily discontinue the dose of metoprolol succinate extended-release tablet.

Until symptoms of worsening heart failure have been stabilized, the dose of metoprolol succinate extended-release tablet should not be increased.

4.3 CONTRAINDICATIONS

Contraindicated in patients with

- Known hypersensitivity to metoprolol succinate or any component of this product.
- Severe bradycardia
- Cardiogenic shock
- Heart block greater than first degree
- Decompensated cardiac failure
- Sick sinus syndrome (unless a permanent pacemaker is in place) and
- Manifest and clinically significant sinus bradycardia (heart frequency < 50/min.)
- Severe peripheral arterial disease.

- Hypotension (systolic < 90 mmHg)
- Metabolic acidosis.
- Severe bronchial asthma or chronic obstructive pulmonary disease.
- Higher grade sinoatrial block
- Metoprolol may not be administered to patients with suspected acute myocardial infarction and a heart rate of < 50 beats/min., PQ interval > 0.24 seconds or systolic blood pressure < 100 mmHg.
- Concomitant intravenous administration of calcium blockers of the type verapamil or diltiazem or other antiarrhythmics (such as disopyramide) is contraindicated (exception: intensive care unit)
- Untreated phaeochromocytoma

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Ischemic Heart Disease:

Following abrupt cessation of therapy with certain beta-blocking agents, exacerbations of angina pectoris and, in some cases, myocardial infarction have been reported. Particularly in patients with ischemic heart disease, the dosage should be gradually reduced over a period of 1–2 weeks and the patient should be carefully monitored, when discontinuing chronically administered metoprolol succinate extended-release tablets.

Metoprolol succinate extended-release tablet administration should be reinstated promptly, at least temporarily, and other measures appropriate for the management of unstable angina should be taken, if angina markedly worsens or acute coronary insufficiency develops.

Bronchospastic Diseases

Patients having bronchospastic diseases should not receive beta-blockers. Metoprolol may be used with caution in patients with bronchospastic disease who do not respond to, or cannot tolerate, other antihypertensive treatment because of its relative beta1-selectivity.

The lowest possible dose of metoprolol should be used and a beta2-stimulating agent should be administered concomitantly, since beta-selectivity is not absolute

Major Surgery

The impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures; the necessity or desirability of withdrawing beta-blocking therapy prior to major surgery is controversial.

With beta-blockers, difficulty in restarting and maintaining the heart beat has also been reported.

Diabetes and Hypoglycemia:

In diabetic patients Metoprolol succinate extended release tablets should be used with caution if a beta-blocking agent is required. Beta-blockers may mask tachycardia occurring with hypoglycemia, but other manifestations such as dizziness and sweating may not be significantly affected. Metoprolol may reduce the effect of diabetes treatment and mask the symptoms of hypoglycaemia Beta-blockers could further increase the risk of severe hypoglycaemia when used concurrently with sulfonylureas. Diabetic patients should be advised to carefully monitor blood glucose levels

Thyrotoxicosis:

Patients suspected of developing thyrotoxicosis should be managed carefully to avoid abrupt withdrawal of beta-blockade, which might precipitate a thyroid storm. Beta-adrenergic blockade may mask certain clinical signs (e.g., tachycardia) of hyperthyroidism.

Peripheral Vascular Disease:
Beta-blockers can precipitate or aggravate symptoms of arterial insufficiency in patients with peripheral vascular disease so caution should be exercised in such individuals.

Calcium Channel Blockers:
Caution should be exercised in patients treated with beta-blockers and calcium channel blockers of the verapamil and diltiazem type concomitantly, because of significant inotropic and chronotropic effects in patients treated with these agents.

Hepatic Function
In patients with impaired hepatic function Metoprolol succinate extended-release tablets should be used with caution.

Cardiac Failure
During up titration of metoprolol succinate extended release tablets, worsening cardiac failure may occur. If such symptoms occur, diuretics should be increased and until clinical stability is restored the dose of metoprolol succinate extended release tablets should not be advanced. It may be necessary to temporarily discontinue or lower the dose of metoprolol succinate extended-release tablet.

Carcinogenesis, Mutagenesis, Impairment of Fertility
In 2-year studies in rats at three oral dosage levels of up to 800 mg/kg/day there was no increase in the development of spontaneously occurring benign or malignant neoplasms of any type.
All genotoxicity tests performed on metoprolol succinate (a Salmonella/mammalian-microsome mutagenicity test) were negative.

Pregnancy
No adequate and well-controlled studies are done in pregnant women, hence, drug should be used during pregnancy only if clearly needed.

Nursing Mothers
The concentration of metoprolol in breast milk is approximately three times higher than the one in the mother's plasma. Even though the risk of adverse effects in the breastfeeding baby would appear to be low after administration of therapeutic doses of the medicinal product (except in individuals with poor metabolic capacity), breastfeeding babies should be monitored for signs of beta blocking..

Pediatric Use
No clinically relevant differences in the adverse event profile were observed for pediatric patients (aged 6 to 16 years) as compared to adults. Safety and effectiveness have not been established in patients < 6 years of age of metoprolol succinate extended release tablets.

Geriatric Use
No established data is present for patients above 65 years of age.

4.5 DRUG INTERACTIONS

The following combinations with metoprolol should be avoided:

Barbituric acid derivatives Barbiturates (studied for pentobarbital) induce the metabolism of metoprolol through enzyme induction.

Propafenon When propafenon was commenced in four patients, who were then treated with metoprolol, the plasma concentrations of metoprolol increased 2-5-fold and two patients suffered typical metoprolol side effects. The interaction was confirmed in a study involving eight healthy research subjects. The interaction is probably due to the fact that propafenon, like quinidine, inhibits the metabolism of metoprolol via cytochrome P450 2D6. The combination is probably difficult to manage due to the fact that propafenon also has beta-receptor blocking properties.

Calcium antagonists In the case of the concomitant use of calcium antagonists of the verapamil or diltiazem types, an increase in negative inotropic and chronotropic effects can occur. Calcium antagonists of the verapamil type should not be administered intravenously to patients who are being treated with beta blockers, due to the risk of hypotension, AV conduction disturbances, and left ventricular insufficiency (see section 4.3). In patients with impaired cardiac function, the combination is contraindicated. As with other beta-blockers, concomitant therapy with dihydropyridines (such as nifedipine and amlodipine), may increase the risk of hypotension, and cardiac failure may occur in patients with latent cardiac insufficiency.

The following combinations with metoprolol may require dose adjustment:

Amiodarone One case history indicates that patients treated with amiodarone can develop severe sinus bradycardia during concomitant treatment with metoprolol. Amiodarone has an extremely long half-life (approximately 50 days), which means that interactions can occur a long time after discontinuation of the preparation.

Class I-antiarrhythmics Class I-antiarrhythmics and beta-receptor blockers have additive negative inotropic effects, which can result in serious haemodynamic adverse reactions in patients with impaired left-ventricular function. The combination should be avoided in “sick sinus syndrome” and pathological AV-conduction. The interaction is best documented for disopyramide.

Non-steroidal anti-inflammatory drugs/antirheumatic agents (NSAID) NSAID-type antiphlogistics counteract the antihypertensive effect of beta-receptor blocking agents. Studies have primarily been performed on indomethacin. This interaction is not believed to occur with sulindac. It has not been possible to demonstrate such an interaction in a study relating to diclofenac.

CYP2D6 inhibitors Metoprolol is a CYP2D6-substrate. Drugs which inhibit this enzyme may increase the plasma concentration of metoprolol. Examples of clinically significant inhibitors of CYP2D6 are antidepressants such as fluoxetine, paroxetine or bupropion, antipsychotics such as thioridazine, antiarrhythmics such as propafenone, antiretrovirals such as ritonavir, antihistamines such as diphenhydramine, antimalarials such as hydroxychloroquine or quinidine, antifungals such as terbinafine and medications for

stomach ulcers such as cimetidine. On commencement of treatment with these medicinal products in patients being treated with metoprolol the dose of metoprolol may need to be reduced.

Diphenhydramine Diphenhydramine reduces (2.5 times) clearance of metoprolol to alpha-hydroxymetoprolol in fast hydroxylaters via CYP 2 D6, at the same time as the effects of metoprolol are increased.

Digitalis glycosides Digitalis glycosides in connection with beta-receptor blockers, can increase the atrioventricular conduction time and induce bradycardia.

Epinephrine A dozen reports exist in respect of severe hypertension and bradycardia in patients treated with non-selective beta-receptor blockers (including pindolol and propanalol), who were administered epinephrine (adrenaline). These clinical observations have been confirmed in studies on healthy research subjects. It has also been suggested that epinephrine, administered as local anaesthesia, may give rise to these reactions on intravasal administration. The risk should be considerably less with cardioselective beta-receptor blockers.

Phenylpropanolamine Phenylpropanolamine (norephedrine) in single doses of 50 mg may increase the diastolic blood pressure to pathological levels in healthy research subjects. In general, propanolol counteracts the rise in blood pressure triggered by phenylpropanolamine. Beta-receptor blockers may, however, trigger paradoxical hypertensive reactions in patients taking high doses of phenylpropanolamine. Hypertensive crises during treatment solely with phenylpropanolamine have been described in a couple of cases.

Quinidine Quinidine inhibits the metabolism of metoprolol in so-called “fast hydroxylaters” (just over 90% in Sweden), with significantly increased plasma values and resultant increase in beta blockade. Similar reaction might be expected to occur with other beta-blockers which are metabolized by the same enzyme (cytochrome P450 2 D6).

Sympathetic ganglion blockers, or other beta blockers Patients who are concomitantly receiving sympathetic ganglion blockers, or other beta blockers (including in the form of eye drops) must continue being monitored.

MAO inhibitors MAO inhibitors should be used with caution as concomitant administration with beta-blockers may result in bradycardia and an enhanced hypotensive effect. Monitoring of blood pressure and heart rate are recommended during initial use.

Centrally-acting antihypertensives (clonidine, guanfacin, moxonidine, methyldopa, rilmenidine) Abrupt withdrawal, particularly if prior to beta-blocker discontinuation, may increase risk of “rebound hypertension”.

The concomitant use of clonidine with a non-selective beta blocker, and possibly also with a selective beta blocker, increases the risk of rebound hypertension. If clonidine is administered concomitantly, the administration of the clonidine medication needs to be continued for some time after beta-blocker therapy is discontinued.

Paroxetine may increase plasma levels of metoprolol resulting in increased beta-blocking effects

Ergotamine As beta-blockers may affect the peripheral circulation, care should be exercised when drugs with similar activity, e.g. ergotamine are given concurrently

Nitrates Nitrates may enhance the hypotensive effect of metoprolol

Parasympathomimetics Concurrent use of parasympathomimetics may result prolonged bradycardia.

Sympathomimetics Metoprolol will antagonize the β1 effect of sympathomimetic agent but should have little influence on the bronchodilator effects of β2 agonists at normal therapeutic dose.

General anaesthetics An increase in the cardio-depressive effect due to the concomitant administration of inhalational anaesthetics is possible; however, since beta blockade can prevent excessive fluctuations in blood pressure whilst the patient is intubated and is rapidly antagonised with beta sympathomimetics, concomitant use is not contraindicated (see section

Insulin and oral antidiabetic agents The blood glucose-reducing effect of insulin and oral blood glucose-reducing drugs can be intensified by beta blockers, in particular non-selective beta blockers. In this case, the dosage of the oral blood glucose-reducing drug must be adjusted.

The concomitant use of beta-blockers with sulfonylureas could increase the risk of severe hypoglycaemia

Alpha blockers such as prazosine, tamsulosin, terazosine, doxazosine Increased risk of hypotension, especially severe orthostatic hypotension.

Floctafenine: Beta blockers may impede the compensatory cardiovascular reactions associated with hypotension or shock that may be induced by floctafenine

Skeletal muscle relaxant Curare muscle relaxant with metoprolol enhanced neuromuscular blockade. Blood pressure should be monitored and dosage adjustment of the antihypertensive be made if necessary.

Lidocaine Metoprolol can reduce the clearance of lidocaine.

Hepatic enzyme inducers Enzyme inducing agents (e.g. rifampicin) may reduce plasma concentrations of metoprolol.

Mefloquine Increased risk of bradycardia

Antacid An increase in the plasma concentrations of metoprolol has been observed when the drug was coadministered with an antacid.

Alcohol During concomitant ingestion of alcohol and metoprolol the concentration of blood alcohol may reach higher levels and may decrease more slowly.

The effects of metoprolol and other antihypertensive drugs on blood pressure are usually additive. Care should be taken when combining with other antihypertensive drugs or drugs that might reduce blood pressure, such as tricyclic antidepressants, barbiturates and phenothiazines. However, combinations of antihypertensive drugs may often be used with benefits to improve control of hypertension.

4.6 USE IN SPECIAL POPULATIONS (SUCH AS PREGNANT WOMEN, LACTATING WOMEN, PAEDIATRIC PATIENTS, GERIATRIC PATIENTS ETC.)

Pregnancy

No adequate and well-controlled studies are done in pregnant women, hence, drug should be used during pregnancy only if clearly needed.

Nursing Mothers

Caution should be exercised when metoprolol succinate extended-release tablet is administered to a nursing woman as it is excreted in breast milk in very small quantities.

Pediatric Use

No clinically relevant differences in the adverse event profile were observed for pediatric patients (aged 6 to 16 years) as compared to adults. Safety and effectiveness have not been established in patients < 6 years of age of metoprolol succinate extended release tablets.

Geriatric Use

No established data is present for patients above 65 years of age.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Patients should be advised to avoid operating automobiles and machinery or engaging in other tasks requiring alertness until the patient's response to therapy with metoprolol succinate extended release tablets has been determined.

4.8 UNDESIRABLE EFFECTS

Metoprolol is well tolerated, and the undesirable effects are generally mild and reversible. The most commonly reported adverse reactions during treatment is fatigue. Gangrene (in patients with severe peripheral circulatory disorder), thrombocytopenia and agranulocytosis may occur very rarely (less than 1 case per 10,000 patients).The following undesirable effects have been reported during the course of clinical studies or have been reported after routine use. In many cases, a link with the use of metoprolol (tartrate) has not been firmly established.

	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)
Blood and lymphatic system disorders					Thrombocytopenia, leukopenia
Endocrine disorders				Deterioration of latent diabetes mellitus.	

Metabolism and nutrition disorders			Weight gain.		
Psychiatric disorders			Depression, concentration problems, drowsiness or insomnia, nightmares.	Nervousness, anxiety.	Forgetfulness or memory impairment, confusion, hallucinations, personality changes (e.g. mood changes).
Nervous system disorders		Dizziness, headache.	Paresthesia.		
Eye disorders				Visual disturbances, dry or irritated eyes, conjunctivitis.	
Ear and labyrinth disorders					Tinnitus, hearing problems.
Cardiac disorders		Bradycardia, balance disturbances (very rarely with associated syncope), palpitations.	Temporary exacerbation of symptoms of heart failure, first-degree atrioventricular block, precordial pain.	Functional heart symptoms, heart arrhythmia, conductivity disturbances.	
Vascular disorders	Pronounced blood pressure drop and orthostatic hypotension, very rarely with syncope.	Cold hands and feet.			Necrosis in patients with severe peripheral vascular disorders prior to treatment, exacerbation of claudicatio intermittens or Raynaud's syndrome.
Respiratory, thoracic and mediastinal disorders		Functional dyspnea.	Bronchospasms.	Rhinitis.	
Gastrointestinal disorders		Nausea, abdominal pain, diarrhoea, constipation.	Vomiting.	Dryness of mouth.	Taste disturbances.
Hepatobiliary				Abnormal	Hepatitis.

disorders				LFT values.	
Skin and subcutaneous tissue disorders			Rash (psoriasislike urticaria and dystrophic cutaneous lesions), increased perspiration.	Hair loss.	Light hypersensitivity reactions, exacerbation of psoriasis, new psoriasis manifestation, psoriasis-like dermatological changes.
Musculoskeletal and connective tissue disorders			Muscle spasms.		Arthralgia, muscle weakness.
Reproductive system and breast disorders				Impotence and other sexual dysfunctions, induratio penis plastica (Peyronie's syndrome).	
General disorders and administration site conditions	Fatigue.		Oedema.		

4.9 OVERDOSAGE

Symptoms:

Overdosage of metoprolol succinate extended-release tablets may lead to

- Cardiac arrest
- Severe hypotension
- Atrioventricular block
- Bronchospasm
- Heart failure
- Cardiogenic shock
- Sinus bradycardia
- Impairment of consciousness/coma
- Nausea, vomiting, and cyanosis.

Treatment

Patients with acute or recent congestive heart or myocardial infarction failure may be more hemodynamically unstable than other patients and should be treated appropriately. The patient should be treated under intensive care conditions whenever possible. The following general measures should be employed on the basis of the pharmacologic actions of metoprolol:

Bradycardia: Atropine should be administered. Isoproterenol should be administered cautiously, if there is no response to vagal blockade.

Hypotension: A vasopressor should be administered, e.g., dopamine
Elimination of the Drug: Perform Gastric lavage.
Bronchospasm: A theophylline derivative and/or a beta-stimulating agent should be administered.
Cardiac Failure: A digitalis glycoside and diuretics should be administered. In shock resulting from inadequate cardiac contractility, administration of isoproterenol, dobutamine, or glucagon may be considered.

5.0 PHARMACOLOGIC PROPERTIES

5.1 MECHANISM OF ACTION

Metoprolol is a beta selective (cardioselective) adrenergic receptor blocking agent. This preferential effect is not absolute, however, and metoprolol also inhibits beta adrenoreceptors at higher plasma concentrations, chiefly located in the vascular musculature and bronchial.

Metoprolol has no intrinsic sympathomimetic activity, and membrane stabilizing activity is detectable only at plasma concentrations much greater than required for beta blockade. Metoprolol slows the sinus rate and decreases AV nodal conduction indicated in animal and human experiments.

5.2 PHARMACODYNAMIC PROPERTIES

Beta-blocking activity of metoprolol in man, is shown by

1. Reduction in heart rate and cardiac output at rest and upon exercise,
2. Reduction of systolic blood pressure upon exercise,
3. Inhibition of isoproterenol-induced tachycardia, and
4. Reduction of reflex orthostatic tachycardia.
   Although beta-adrenergic receptor blockade is useful in the treatment of hypertension, angina, and heart failure there are situations in which sympathetic stimulation is vital. Adequate ventricular function may depend on sympathetic drive in patients with severely damaged hearts. Beta-blockade may prevent the necessary facilitating effect of sympathetic activity on conduction in the presence of AV block.

5.3 PHARMACOKINETIC PROPERTIES

Parameters	Metoprolol succinate extended release
Absorption	The peak plasma concentrations (Cmax) of metoprolol is observed within 10-12 hours and 2.0 hours of dose intake, respectively For AUC, the mean values were 0–24 ($P<0.05$) Metoprolol is a racemic mixture of R- and S- enantiomers, and is primarily metabolized by CYP2D6. When administered orally, it exhibits stereo selective metabolism that is dependent on oxidation phenotype.CYP2D6 can be inhibited by a number of drugs. Concomitant use of inhibiting drugs in poor metabolizers will increase blood levels of Metoprolol several-fold, decreasing Metoprolol's cardioselectivity
Distribution	Metoprolol crosses the blood-brain barrier and has been reported in the CSF in a concentration 78% of the simultaneous plasma concentration. Volume of distribution of 5.6 L/kg.
Metabolism	Metoprolol is a racemic mixture of R- and S- enantiomers, and is primarily metabolized by CYP2D6. When administered orally, it exhibits stereoselective

	metabolism that is dependent on oxidation phenotype.CYP2D6 can be inhibited by a number of drugs. Concomitant use of inhibiting drugs in poor metabolizers will increase blood levels of Metoprolol several-fold, decreasing Metoprolol's cardioselectivity.
Excretion	Elimination is mainly by biotransformation in the liver, and the plasma half-life ranges from approximately 3 to 7 hours. Less than 5% of an oral dose of Metoprolol is recovered unchanged in the urine; the rest is excreted by the kidneys as metabolites that appear to have no beta-blocking activity.
Half life	The plasma half-life ranges from approximately 3 to 7 hours.
Plasma protein binding	Plasma protein binding of metoprolol is about 5-10%.

6. NONCLINICAL PROPERTIES

6.1 ANIMAL TOXICOLOGY OR PHARMACOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

In 2-year studies in rats at three oral dosage levels of up to 800 mg/kg/day there was no increase in the development of spontaneously occurring benign or malignant neoplasms of any type.

All genotoxicity tests performed on metoprolol succinate (a *Salmonella*/mammalian-microsome mutagenicity test) were negative.

7. DESCRIPTION

Supermet™ XL 25 :

SUPERMET XL 25 is supplied for oral administration, as an extended - release tablet of Metoprolol Succinate. Each extended - release tablet of SUPERMET XL 25 contains Metoprolol Succinate 23.75 mg, equivalent to Metoprolol Tartrate 25 mg.

Supermet™ - XL 50

SUPERMET XL 50 is supplied for oral administration, as an extended - release tablet of Metoprolol Succinate. Each extended - release tablet of SUPERMET XL 50 contains Metoprolol Succinate 47.5 mg, equivalent to Metoprolol Tartrate 50 mg.

Supermet™ XL 100

SUPERMET XL 100 is supplied for oral administration, as an extended - release tablet of Metoprolol Succinate. Each extended - release tablet of SUPERMET XL 100 contains Metoprolol Succinate 95 mg, equivalent to Metoprolol Tartrate 100 mg.

8. PHARMACEUTICAL PARTICULARS

8.1 INCOMPATIBILITIES

Not Applicable

8.2 SHELF-LIFE

Refer pack

8.3 PACKAGING INFORMATION

Refer pack

8.4 STORAGE AND HANDING INSTRUCTIONS
Refer pack

9. PATIENT COUNSELLING INFORMATION
Take metoprolol succinate extended-release tablets regularly and continuously, as directed, preferably with or immediately following meals.

If a dose should be missed, take only the next scheduled dose (without doubling it).

Do not interrupt or discontinue metoprolol succinate extended-release tablets without consulting the physician.
Avoid operating automobiles and machinery or engaging in other tasks requiring alertness until your response to therapy with metoprolol succinate extended release tablets has been determined

Contact your physician if any difficulty in breathing occurs

Inform the physician or dentist before any type of surgery that you are taking metoprolol succinate extended-release tablets.

If you are a heart failure patient, you should consult your physician if you experience signs or symptoms of worsening heart failure such as weight gain or increasing shortness of breath.

10. DETAILS OF MANUFACTURER
Refer Pack for manufacturer details.

Marketed By
Abbott Healthcare Pvt. Ltd.
Angel Space, Bldg. D-4, Gala No. 1 to 3 & 11 to 13 Ground Floor, 101 to 106 & 111 to 116 First Floor, 201 to 206 & 211 to 216 2nd Floor, Pimplas, Dist. Thane, Bhiwandi-421 302, Maharashtra, India.

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11. DETAILS OF PERMISSION OR LICENCE NUMBER
Refer Pack for Permission/License details.

12. DATE OF REVISION
Version 5.0, dated 10th April 2026

For Product Complaints/Adverse events or Queries please write to
webmasterindia@abbott.com