Summary of Product Characteristics (SPC)

1. Name of the medicinal product

1.1 (Invented) Name of the medicinal product
CILNEED 20

1.2 Strength
Each Film coated tablet contains:
Cilnidipine 20 mg
Excipients Q.S.
Colour: Titanium Dioxide

1.3 Pharmaceutical Form

Film coated Tablet

2. Qualitative and Quantitative Formula

Batch size: 100,000 Tablets

Sr. No.	Name of raw material	Spec.**	Qty./Tab (mg)	Qty./batch (kg)	Functions
Dry Mixing					
1	Starch	BP	335.00	33.50	Diluent
2	Lactose	BP	200.00	20.00	Binder
Wet Granulation					
3	PVP K 30	BP	12.00	1.20	Binder
4	Purified water	BP	0.06 ml	6.0 Lit.	Solvent
Lubrication					
5	Cilnidipine	IHS	20.00	2.00	Calcium channel blockers
6	Magnesium Stearate	BP	8.00	0.80	Lubricant
7	Purified Talc	BP	5.00	0.50	Glidant
8	Fumed Silica	BP	5.00	0.50	Lubricant
9	Sodium Starch Glycolate	BP	15.00	1.50	Disintegrant
Average weight of uncoated tablet			**600.00 mg**	**60.00 kg**	
Coating					
10	Hydroxy propyl methylcellulose	BP	9.00	0.90	Film former
11	Purified Talc	BP	1.50	0.15	Plasticizer
12	Polyethylene Glycol 4000	BP	1.50	0.15	Plasticizer
13	Titanium Dioxide	BP	1.00	0.10	Colorant
14	Methylene Chloride	BP	0.20 ml	20.0 Lit.	Solvent
15	Isopropyl Alcohol	BP	0.14 ml	14.0 Lit.	Solvent
Average Weight of coated Tablet			**613.00 mg**	**61.30 kg**	

** Latest Edition.
*** The materials that will not remain in the final product.

3. Pharmaceutical form

A White coloured round shaped biconcave both side plain film coated tablets.

4. Clinical particulars

4.1 Therapeutic Indication:

CILNEED 20 is indicated for the **t**reatment of hypertension.
Cilnidipine is a calcium channel blocker prescribed for patients at risk of vascular damage caused by hypertension. It comes in the form of a tablet, and helps to control hypertension (high blood pressure) by reduce the functioning of the body`s angiotensin receptors.

4.2 Contraindications

Cardiogenic shock
Recent MI
Acute unstable angina
Severe arotic stenosis
Hyper sensitivity

4.3 Special warnings and precautions for use:

1. If you have an allergic or hypersensitive reaction, seek emergency medical attention.

2. Possible symptoms include difficulty breathing, difficulty swallowing, swelling, chest tightness, skin rashes, and hives.

3. This medication should only be used as instructed and prescribed by your physician or pharmacist. Do not alter your dosage unless specifically instructed to do so by either of the above.

4. Dosage and usage often depends on the severity of the condition, as well as the patient’s medical history and current health condition.

5. Before you begin using this medication, ensure your physician is aware of the following:

If you are pregnant or breastfeeding.
If you have any allergies.
If you have any other illnesses, disorders, or medical conditions.
If you are using any other drugs or medication.
If you are using any vitamins or supplements.

Hypotension, poor cardiac reserve, heart failure. Sudden withdrawal may exacerbate angina. Discontinue in patients who experience ischemic pain following administration. Pregnancy, lactation.

4.4 Interaction with other medicinal products and other forms of interaction

Other antihupertensive
Aldesleukin
Anyiphyscotics that cause hypotension
May modify insulin and glucose responses
Quinidine
Carbamazepine
Phenytoin
Rifampicin
Cimetidine
Erythromycin

4.5 Adverse Drug Reactions

>Possible side effects of Cilnidipine are listed below. Inform your doctor if you notice any adverse effects whether listed below or not.

- Nausea
- Headaches
- Trouble breathing
- Swelling
- Low blood pressure
- Edema (water retention)
- Dizziness
- Flushing
- Headache
- Hypotension
- Peripheral oedema
- Tachycardia
- Palpitation
- GI disturbance
- Increased micturition frequency
- Lethargy
- Eye pain
- Depression
- Ischaemic chest pain
- Cerebral or myocardial ischaemia
- Ransient blindness
- Rashes
- Fever
- Abnormal liver function
- Gingival hyperplasia
- Myalgia
- Tremor
- Impotence

5. Pharmacological properties

Pharmacotherapeutic Group
Antihypertensive agents, Calcium Antagonists

ATC code
C08CA14

5.2 Pharmacodynamic properties

Mechanism of Action

Cilnidipine is a dihydropyridine calcium channel blocker. It inhibits cellular influx of calcium, thus causing vasodilatation. It has greater selectivity for vascular smooth muscle. It has little or no action at the SA or AV nodes and –ve inotropic activity is rarely seen at the therapeutic doses.

Cilnidipine is a vascular selective calcium antagonist, which lowers arterial blood pressure by decreasing peripheral vascular residence. Due to the high degree of selectivity for smooth muscle in the arterioles, Cilnidipine in therapeutic doses has no direct effect on cardiac contractility or conduction.
It can be used as monotherapy or in combination with other antihypertensive drugs, e.g. β-receptor blockers, diuretics or ACE-inhibitors, in order to achieve an increased antihypertensive effect. Cilnidipine reduces both systolic and diastolic blood pressure and can be used in isolated systolic hypertension. In a study of 12 patients, Cilnidipine maintained its antihypertensive effect during concomitant therapy with indomethacin.
Because there is no effect on venous smooth muscle or adrenergic vasomotor control, Cilnidipine is not associated with orthostatic hypotension.
Cilnidipine has anti-anginal and anti-ischaemic effects due to improved myocardial oxygen supply/ demand balance. Coronary vascular resistance is decreased and coronary blood flow as well as myocardial oxygen supply is increased by Cilnidipine due to dilation of both epicardial arteries and arterioles. Cilnidipine effectively counteracts coronary vasospasm. The reduction in systemic blood pressure caused by Cilnidipine leads to decreased left ventricular after load.
Cilnidipine improves exercise tolerance and reduces anginal attacks in patients with stable effort induced angina pectoris. Both symptomatic and silent myocardial ischaemia are reduced by Cilnidipine in patients with vasospastic angina. Cilnidipine can be used as monotherapy or in combination with β-receptor blockers in patients with stable angina pectoris.
Cilnidipine possesses a mild natriuretic/diuretic effect and generalised fluid retention does not occur.
There is limited clinical trail experience of the use of Cilnidipine in hypertensive paediatric patients. In a randomised, double-blind, 3-week, parallel group study in children aged 6-16 years with primary hypertension, the antihypertensive effects of once daily Cilnidipine 2.5mg (n=33), 5mg (n=33) and 10mg (n=31) were compared with placebo (n=35). The study failed to demonstrate the efficacy of Cilnidipine in lowering blood pressure in children aged 6-16 years.
The long term effects of Cilnidipine on growth, puberty and general development have not been studied. The long term efficacy of antihypertensive therapy as therapy in childhood to reduce cardiovascular morbidity and mortality in adulthood has also not been established.

Cilnidipine is well tolerated in patients with concomitant disease such as congestive heart failure well controlled on appropriate therapy, asthma and other obstructive pulmonary diseases, diabetes, gout, hyperlipidemia impaired renal function, renal transplant recipients and Raynaud's disease. Cilnidipine has no significant effect on bland glucose levels or lipid profiles.

Haemodynamic effects: The primary haemodynamic effect of Cilnidipine is a reduction of total peripheral vascular resistance which leads to a decrease in blood pressure. These effects are dose- dependent. In patients with mild to moderate essential hypertension, a reduction in blood pressure usually occurs 2 hours after the first oral dose and lasts for at least 24 hours with a trough/peak ratio usually above 50%.

Plasma concentration of Cilnidipine and decrease in total peripheral resistance and blood pressure are positively correlated.

Electrophysiological and other cardiac effects: Cilnidipine in therapeutic doses has no effect on cardiac contractility or atrioventricular conduction or refractoriness.

Renal effects: Cilnidipine has a natriuretic and diuretic effect. Studies have shown that the tubular reabsorption of filtered sodium is reduced. This counteracts the salt and water retention observed for other vasodilators. Cilnidipine does not affect the daily potassium excretion. The renal vascular resistance is decreased by Cilnidipine. Normal glomerular filtration rate is unchanged. In patients with impaired renal function glomerular filtration rate may increase.

Cilnidipine is well tolerated in renal transplant recipients.

Site and mechanism of action: The predominant pharmacodynamic feature of Cilnidipine is it’s pronounced vascular versus myocardial selectivity. Myogenically active smooth muscles in arterial resistance vessels are particularly sensitive to Cilnidipine.

Cilnidipine inhibits electrical and contractile activity of vascular smooth muscle cells via an effect on the calcium channels in the cell membrane.

5.3 Pharmacokinetic properties

Absorption and distribution: Cilnidipine is completely absorbed from the gastrointestinal tract after administration of Cilnidipine extended release tablets.

The systemic availability of Cilnidipine is approximately 15% in man and is independent of dose in the therapeutic dose range.

The plasma protein binding of Cilnidipine is approximately 99%. It is bound predominantly to the albumin fraction.

Elimination and metabolism: The average half-life of Cilnidipine in the terminal phase is 1.8-2.2 hours. There is no significant accumulation during long-term treatment. Cilnidipine is extensively metabolised by the liver and all identified metabolites are inactive. Elderly patients and patients with reduced liver function have an average higher plasma concentration of Cilnidipine than younger patients.

About 70% of a given dose is excreted as metabolites in the urine; the remaining fraction is excreted in the faeces. Less than 0.5% of a dose is recovered unchanged in the urine.

The kinetics of Cilnidipine is not changed in patients with renal impairment.

6. Pharmaceutical particulars

6.1 List of Excipients

Name of excipients
Starch
Lactose
PVP K 30
Purified water
Magnesium Stearate
Purified Talc
Fumed Silica
Sodium Starch Glycolate
Hydroxy propyl methylcellulose
Polyethylene Glycol 4000
Titanium Dioxide
Methylene Chloride
Isopropyl Alcohol

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

36 months from the date of manufacturing.

6.4 Special precautions for storage

Store below 30°C. Keep all medicines out of reach of children.

6.5 Nature and contents of container

CILNEED 20 is packed in 3 X 10 Alu - Alu Blisters in printed carton along with package insert.

6.6 Special precautions for disposal

No special requirements

7. **REGISTRANT**
PHARMA SPECIALITIES LTD
P.O. Box 49146 - 00100
Nairobi, Kenya

8. **MANUFACTURER**
SWISS PHARMA PVT.LTD.
Address: Plot No- 3709, GIDC,
Phase-IV, Vatva, Dist-Ahmedabad-382 445,
Gujarat, Country: India.

9. **DATE OF REVISION OF THE TEXT:**
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10. **NAME AND ADDRESS OF MANUFACTURER**
SWISS PHARMA PVT.LTD.
Address: Plot No- 3709, GIDC,
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