

# MYOSPAZ<sup>®</sup> (CHLORZOXAZONE AND PARACETAMOL TABLETS)

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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**Read all of this leaflet carefully before you start taking this medicine, because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider or pharmacist.

### What is in this leaflet?

1. What Myospaz is and what it is used for?
2. What you need to know before you take Myospaz?
3. How to take Myospaz?
4. Possible side effects?
5. How to store?
- 6 Contents of the pack and other information

### 1. What Myospaz tablets is and what it is used for?

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Myospaz contains the active ingredients Chlorzoxazone and Paracetamol. The combined analgesic effect of paracetamol and the muscle relaxant action of chlorzoxazone provides in-depth relief from pain associated with skeletal muscle spasm.

Chlorzoxazone USP is a centrally acting skeletal muscle relaxant, available as tablets of 250 mg for oral administration. Its chemical name is 5-Chloro-2-benzoxazolinone.

Paracetamol is an analgesic and an antipyretic which means it relieves pain and reduces high temperature and fever.

These tablets are used for the relief of:

- mild to moderate pain including headache, migraine, sharp nerve pain (neuralgia), toothache, sore throat, period pains, aches and pains.
- rheumatic aches and pains, influenza symptoms, feverishness, and feverish colds

### 2. What you need to know before you take Myospaz tablets?

Do not take Chlorzoxazone Tablets if you:

- are allergic to Chlorzoxazone or any other ingredients of Chlorzoxazone Tablets (listed in section 6). Signs of a hypersensitivity reaction include swelling of the face and mouth (angioedema), breathing problems, chest pain, runny nose, skin rash or any other allergic type of reaction.
- have now, or have ever had, a stomach (gastric) or duodenal (peptic) ulcer, or bleeding in the digestive tract (this can include blood in vomit, bleeding when emptying bowels, fresh blood in faeces or black, tarry faeces)
- have had stomach or bowel problems after you have taken other muscle relaxant
- have severe heart, kidney or liver failure

- have established heart disease and/or cerebrovascular disease e.g. if you have had a heart attack, stroke, mini-stroke (TIA) or blockages to blood vessels to the heart or brain or an operation to clear bypass blockages
- have or have had problems with your blood circulation (peripheral arterial disease)
- are more than six months pregnant.

Do not take Paracetamol tablets if you:

- are allergic to paracetamol or any other ingredients (these are listed in Section 6, Further Information) for example sodium metabisulphite contained in these tablets may rarely cause severe hypersensitivity reactions and bronchospasm (breathing difficulties)
- are taking any other paracetamol-containing products

### **Warnings and Precautions**

Talk to your doctor, nurse, or pharmacist before you are given this Myospaz Tablet:

Myospaz Tablet should be given with care to patients with impaired kidney or liver function. Large doses should be avoided in patients with hepatic impairment. Do not exceed recommended dose. It should be given with care to patients with alcohol dependence.

### **Pregnancy and breast-feeding**

- You should let your doctor know if you are pregnant or breast-feeding or wish to become pregnant or start breastfeeding whilst taking this medicine.
- Ask your doctor or pharmacist for advice before taking any product.

### **Driving and using machines**

It is advisable not to drive or operate machinery if visual disturbances, headaches, dizziness, or drowsiness occur whilst taking Myospaz Tablets.

### **3. How to take Myospaz Tablets?**

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You should check with your doctor or pharmacist if you are not sure. The usual dose is:  
Adult: 1 or 2 tablets 3 or 4 times a day, according to the intensity of pain and spasm.

Children: 7 to 12 years: 1/2 to 1 tablet 3 or 4 times a day or according to the physician's directions.

As improvement occurs, dosage can usually be reduced.

### **If you take more Myospaz tablets than recommended**

Contact your nearest hospital casualty department or your doctor immediately. Take this leaflet and the packaging with you so that the doctor knows what you have taken. Symptoms of an overdose are headache, feeling sick, being sick, stomach pain, intestinal bleeding, diarrhoea, disorientation, excitation, coma, drowsiness, dizziness, fits, ringing in the ears and fainting.

## **If you forget to take Myospaz tablets**

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten dose. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **4. Possible side effects?**

Like all medicines, **Myospaz Tablets** can cause side effects, although not everybody gets them.

Cardiac Disorders:

Very Rare: Palpitations, chest pain, cardiac failure, myocardial infarction.

Vascular Disorders:

Very Rare: vasculitis.

Respiratory, thoracic and mediastinal disorders:

Rare: Asthma (including dyspnea)

Very Rare: Pneumonitis

Gastrointestinal Disorders:

Common: Nausea, vomiting, diarrhoea, dyspepsia, abdominal pain, flatulence, anorexia.

Rare: Gastritis, gastrointestinal haemorrhage, haematemesis, diarrhoea haemorrhagic, malaena, gastrointestinal ulcer (with or without bleeding or perforation).

Very Rare: Colitis (including haemorrhagic colitis and exacerbation of ulcerative colitis or Crohn's disease), constipation, stomatitis, glossitis, oesophageal disorder, diaphragm – like intestinal strictures, pancreatitis.

Hepatobiliary disorders:

Common: Transaminases increased.

Rare: Hepatitis, jaundice, liver disorder.

Very Rare: Hepatic necrosis, Hepatic failure.

Skin and subcutaneous tissue disorders:

Common: Rash.

Rare: Urticaria.

Very Rare: Eczema, Erythema, Erythema multiforme, Stevens – Johnson purpura, allergic purpura, pruritus.

Renal and Urinary disorders:

Very Rare: Acute renal failure, haematuria. Proteinuria, nephrotic syndrome, interstitial nephritis, renal papillary necrosis.

## **5. How to store Myospaz Tablets?**

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Keep this medicine out of the sight and reach of children.

Store protected from light & moisture at a temperature not exceeding 30° C.

Do not use this medicine after the expiry date which is stated on the blister strip and carton.

The expiry date refers to the last day of that month.

## 6. Other information

### What Myospaz Tablets contains?

- Each uncoated tablet contains:  
Chlorzoxazone USP : 250 mg  
Paracetamol BP : 500 mg
- The other ingredients are Croscarmellose Sodium, Colloidal Anhydrous Silica, Gelatin, Magnesium Stearate, Microcrystalline Cellulose, Potassium Sorbate, Povidone K-30, Sodium Starch Glycollate, Starch, Talc.

### What Myospaz tablets looks like and contents of the pack?

White, biconvex, uncoated, caplet shaped, scored tablets.

**Myospaz Tablets:** Box of 100 Tablets (10 blister strips of 10 tablets each)

### Marketed by:

Win-Medicare Pvt. Ltd.  
1400, Modi Tower,  
98, Nehru Place,  
New Delhi – 110019, India.

### Manufactured by:

Win-Medicare Pvt. Ltd.  
Modipuram – 250 110,  
U.P., India.



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