

## Information sheet

### Food for Special Medical Purposes For Cancer Patients

#### What is Culevit Forte for Cancer Patients Powder for Oral Solution?

Culevit Forte for Cancer Patients Powder for Oral Solution is a food for special medical purposes for cancer patients.

The active components of Culevit Forte for Cancer Patients Powder for Oral Solution (hereinafter briefly as Culevit Forte powder) - specific amino acids (L-Arginine, L-Phenylalanine, L-Histidine, L-Tryptophan, L-Methionine, L-Tyrosine), certain vitamins (C, B<sub>6</sub>, B<sub>12</sub>, Biotin) and other components (L-Malic acid, Adenine, Glucosamine, Lipoic acid) - are substances also present in our circulatory system. Culevit Forte powder provides increased intake of these essential and important substances.

The daily dosage of the powder (1 sachet/day) contains the same quantity of active ingredients as the daily dosage of the Culevit Forte for Cancer Patients Tablet (15×2=30 tablets/day).

Since Culevit Forte powder is sugar-free, it may also be taken by diabetics and patients with lactose intolerance.

Culevit Forte powder should be administered every day, continuously without interruption.

#### What are the components of Culevit Forte powder?

1 sachet contains 4.7 g of L-Arginine, 2.29 g of Vitamin C, 1.65 g of L-Phenylalanine, 1.63 g of L-Histidine, 1.27 g of L-Malic acid, 1.16 g of L-Tryptophan, 0.39 g of L-Methionine, 0.113 g of Adenine, 0.09 g of Glucosamine, 0.064 g of L-Tyrosine, 0.05 g of Vitamin B<sub>6</sub>, 0.041 g of Lipoic acid, 0.04 g of Vitamin B<sub>12</sub>, 4.5 mg of flavouring (4-Hydroxybenzoic acid,  $\alpha$ -keto-Leucine, Cinnamic acid,  $\alpha$ -keto-Phenylalanine,  $\alpha$ -keto-Isoleucine) and 1.50 mg of Biotin.

#### What else does the product contain?

It contains colloidal silicon dioxide (free-flow agent) as an excipient.

#### When is the use of the product recommended?

The administration of Culevit Forte powder is recommended for the dietary provision of patients suffering from malignant tumourous disease, to complement their cancer treatment.

#### When should the administration of the product be avoided?

If you are allergic to any of the ingredients or excipients you should not consume the product! Patients with phenylketonuria should not administer it because the product contains Phenylalanine. Avoid using the product in case of hyperhomocysteinemia and homocystinuria because it contains Methionine.

#### Is there anything to know before taking the product?

The product should not be used as a sole source of nourishment!

#### Is the product suitable for children?

No, the powder is not recommended for children. In order to prevent children from using the product – for their safety - it should be kept out of their reach. If necessary, Culevit Forte tablet can be taken, dosage depends on bodyweight.

#### Can the product be used together with other medications?

Yes, the product can be used with the vast majority of drugs - without the risk of unpleasant and/or harmful interactions.

However, Tryptophan intake should be avoided with the concomitant use of some pharmaceutical products, eg. serotonin reuptake inhibitors (SSRI) used for depression; immunomodulatory products (eg. Interferon). In such cases, consult your physician before taking this product.

## What to consider during pregnancy and breastfeeding?

No data is available related to taking large quantities of the product in such conditions. Pregnant and breastfeeding women are advised to consult their physician (obstetrician-gynecologist, respectively pediatrician) prior to taking the product.

## What is the recommended dosage?

For adults, it is recommended to administer 1-2 sachets a day after dissolution.

## How and when should the product be administered?

Cancer patients should take the recommended dosage once every hour, evenly distributed throughout the day, from waking up until going to sleep. The powder should be administered continuously, without interruption before, during and after oncology treatments.

## How to prepare the solution?

1-2 sachets of powder should be dissolved in 600 ml of non-carbonated water. 50 ml of this solution should be administered every hour during the day (12x50 ml a day). By stirring continuously, the complete dissolution should take a few minutes (caused by the slower dissolution of the free-flow agent).

## How to store the prepared solution and how long can it be stored?

The sealed bottle filled with the solution should be stored away from light and heat, in a fridge (5-7 °C), in a dark, heat-retaining bottle or in a vacuum flask. The first 50 ml of the solution should be administered after preparation, the rest should be consumed within 12 hours.

## What side-effects can be caused by the product?

No side-effects are known if used in the recommended dosage.

## What else needs to be considered when taking the product?

The use of Culevit Forte powder requires individual consideration in case of existing gastric and duodenal ulcers, and extreme gastric hyperacidity.

In case of hypothyroidism or hyperthyroidism, consult your endocrinologist before administering the powder (because of the L-Phenylalanine and L-Tyrosine content of the product).

If you suffer from a very uncommon disease associated with serotonin-producing carcinoid cancer, ask your physician for advice (because of the Tryptophan content of the product).

Patients undergoing renal dialysis or suffering from severe hepatic failure should consult a urologist or respectively a hepatologist/gastroenterologist.

## How long can the product be taken?

As long as the tumour is still detectable, the product should be administered continuously (1-2 sachets/day). If the tumour can no longer be traced, it is advised to continue the administration of the powder: for 6 more months with a required dosage of 1-2 sachets/day, then for at least another 6 months with 1 sachet/day.

## How to store Culevit Forte powder?

The product is a yellowish-white powder filled in sachets, and respectively packed in a box. It should be stored in a dry place, at room temperature (15-25 °C). The powder is very sensitive to humidity, therefore it can only be stored in the original unopened sachet! During storage, the powder can aggregate in the unopened sachet, but it does not influence the effectiveness of the product.

**Should you have any further questions regarding the consumption of the product, please contact Culevit Information Service at +36 1 321 2111. • (Internet: [www.culevit.hu](http://www.culevit.hu))**

Packaging:	30 sachets/box
Net weight:	409.2 g (30 pcs of 13.64 g sachets)
Best before:	The date indicated on the box.
Manufactured and distributed by:	Culevit Ltd. 1077 Budapest, Wesselényi str. 16. Building C., 1 <sup>st</sup> floor, Hungary
Notification number:	T/1907/2014