

# Empower Diabetes Patient

## GLYCIPHAGE®

Metformin 250 mg Tablets, 500 mg & 850 mg Press Tablets

## GLYCIPHAGE SR®

Metformin 500 mg, 850 mg & 1000 mg Sustained Release Tablets



## GLYCIPHAGE® G 1mg / 2mg

Metformin SR 500 mg + Glimepiride 1 mg / 2 mg

## GLYCIPHAGE® VG

Metformin SR 500 mg + Voglibose 0.2 mg + Glimepiride 1 mg / 2 mg Tablets

## Voliphage™

Voglibose 0.2 mg / 0.3 mg Tablets

## GLYCIPHAGE® G 1mg / 2mg FORTE

Metformin SR 1000 mg + Glimepiride 1 mg / 2 mg

## Voliphage-M™

Metformin SR 500 mg + Voglibose 0.2 mg / 0.3 mg Tablets

## FOXSTAT™

Febuxostat 40 mg / 80 mg Tablets

## DAVIT™ plus

## POZITIV®

Pioglitazone Hydrochloride 7.5 mg, 15 mg Tablets

## POZITIV-G™ 1mg / 2mg

Pioglitazone 15 mg + Glimepiride 1 mg / 2 mg Tablets

## BENALGIS®

Benfotiamine 100 mg Tablets

## PRENEUROLIN™ PLUS

Pregabalin 75 mg and Mecobalamin 750 mcg Capsules

DIABÉTIX

A Division of  
FRANCO-INDIAN  
PHARMACEUTICALS PVT. LTD.

# CDSCO Issues Draft Clinical Trials Rules, 2018

KK AGGARWAL

## **SEVENTH SCHEDULE**

### **Formulae to Determine the Quantum of Compensation in the Cases of Clinical Trial Related Injury or Death**

#### **1. Formula in case of clinical trial related death:**

Compensation =  $(B \times F \times R)/99.37$

Where,

B = Base amount (i.e. 8 lacs)

F = Factor depending on the age of the trial subject as per Annexure 1 (based on Workmen Compensation Act)

R = Risk Factor depending on the seriousness and severity of the disease, presence of comorbidity and duration of disease of the trial subject at the time of enrollment in the clinical trial between a scale of 0.5 to 4 as under:

- (1) 0.5: Terminally ill patient (expected survival not more than (NMT) 6 months)
- (2) 1.0: Patient with high risk (expected survival between 6 to 24 months)
- (3) 2.0: Patient with moderate risk
- (4) 3.0: Patient with mild risk
- (5) 4.0: Healthy Volunteers or trial subject of no risk.

However, in case of patients whose expected mortality is 90% or more within 30 days, a fixed amount of Rs. 2 lacs should be given.

#### **2. Formula in case of clinical trial related injury (other than death):**

For calculation of quantum of compensation related to injury (other than death), the compensation shall be linked to the criteria considered for calculation of compensation in cases of death of the trial subject as referred to in section of this Schedule.

The quantum of compensation in case of Clinical Trial related SAE (serious adverse event) should not

exceed the quantum of compensation which would have been due for payment in case of death of the trial subject since the loss of life is the maximum injury possible. As per the definition of SAE, the following sequelae other than death are possible in a clinical trial subject, in which the trial subject shall be entitled for compensation in case the SAE is related to clinical trial.

#### **(i) A permanent disability**

In case of SAE causing permanent disability to the trial subject, the quantum of compensation in case of 100% disability shall be 90% of the compensation which would have been due for payment to the nominee(s) in case of death of the trial subject.

The quantum for less than 100% disability will be proportional to the actual percentage disability the trial subject has suffered.

Accordingly, following formula shall be applicable for determination of compensation:

$$\text{Compensation} = (C \times D \times 90)/(100 \times 100)$$

Where,

D = Percentage disability the trial subject has suffered.

C = Quantum of Compensation which would have been due for payment to the trial subject's nominees) in case of death of the trial subject.

#### **(ii) Congenital anomaly or birth defect**

The congenital anomaly or birth defect in a baby may occur due to participation of anyone or both the parent in clinical trial. Following situations may arise due to congenital anomaly or birth defect.

- (a) Still birth;
- (b) Early death due to anomaly;
- (c) No death but deformity which can be fully corrected through appropriate intervention;
- (d) Permanent disability (mental or physical).

The compensation in such cases would be a lump sum amount such that if that amount is kept by way of fixed deposit or alike, it shall bring a monthly interest amount which is approximately equivalent to half of minimum wage of the unskilled worker (in Delhi).

The quantum of compensation in such cases of SAE shall be half of the base amount as per formula for determining the compensation for SAE resulting into death.

In case of birth defect leading to sub-clause (c) & (d) of this clause to any child, the medical management as long as required shall be provided by the Sponsor or his representative which will be over and above the financial compensation.

**(iii) Chronic life-threatening disease**

**(iv) Reversible SAE in case it is resolved**

In case of clinical trial related SAE causing life-threatening disease and reversible SAE in case it is resolved, the quantum of compensation would be linked to the number of days of hospitalization of the trial subject. The compensation per day of hospitalization shall be equal to the wage loss. The wage loss per day

shall be calculated based upon the minimum wage of the unskilled worker (in Delhi).

Since, in case of hospitalization of any patient not only the patient loses his/her wage, there will be direct or indirect losses of various kind including inconvenience, wage loss of attendant, etc. The compensation per day of hospitalization in such case shall be double the minimum wage.

Accordingly, following formula shall be applicable for determination of compensation:

$$\text{Compensation} = 2 \times W \times N$$

Where,

W = Minimum wage per day of the unskilled worker (in Delhi)

N = Number of days of hospitalization.

### ANNEXURE-1

**Factor (F) for Calculating the Amount of Compensation**

Age 1	Factor (F) 2	Age 1	Factor (F) 2	Age 1	Factor (F) 2
Not more than...		32	203.85	49	156.47
16	228.54	33	201.66	50	153.09
17	227.49	34	199.40	51	149.67
18	226.38	35	197.06	52	146.20
19	225.22	36	194.64	53	142.68
20	224.00	37	192.14	54	139.13
21	222.71	38	189.56	55	135.56
22	221.37	39	186.90	56	131.95
23	219.95	40	184.17	57	128.33
24	218.47	41	181.37	58	124.70
25	216.91	42	178.49	59	121.05
26	215.28	43	175.54	60	117.41
27	213.57	44	172.52	61	113.77
28	211.79	45	169.44	62	110.14
29	209.92	46	166.29	63	106.52
30	207.98	47	163.07	64	102.93
31	205.95	48	159.80	65 or more	99.37

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