

# DABICLOT

Dabigatran Etexilate 110/ 150 mg Capsule

## CLINICAL PHARMACOLOGY

**Pharmaco-therapeutic Group:** Antithrombotic agents, Direct Thrombin Inhibitors.

**Mechanism of Action:** Dabigatran is a potent, competitive, reversible direct thrombin inhibitor and is the main active principle in plasma. Since thrombin (serine protease) enables the conversion of fibrinogen into fibrin during the coagulation cascade, its inhibition prevents the development of thrombus. Dabigatran inhibits free thrombin, fibrin-bound thrombin and thrombin-induced platelet aggregation.

## DRUG-DRUG INTERACTIONS:

- Amiodarone, Dronedarone, medicines used to treat irregular heartbeats
- Verapamil, a calcium channel blocker used to treat high blood pressure and angina
- Clarithromycin or rifampicin, medicines used to treat infections
- Selective serotonin re-uptake inhibitors (SSRI), selective serotonin norepinephrine re-uptake inhibitors (SNRI), medicines used to treat mood disorders.

## INDICATIONS:

- Reduction of Risk of Stroke and Systemic Embolism in Non-Valvular Atrial Fibrillation
- Treatment of Deep Venous Thrombosis and Pulmonary Embolism and its recurrence
- Prophylaxis of Deep Vein Thrombosis and Pulmonary Embolism Following Hip Replacement Surgery

## SPECIAL POPULATIONS:

**Patients at risk of bleeding:** Dose adjustment should be decided at the discretion of the physician, following assessment of the potential benefit and risk to an individual patient. For patients with gastritis, esophagitis, or gastro esophageal reflux, a dose reduction may be considered due to the elevated risk of major gastro-intestinal bleeding.

**Renal impairment:** Treatment with DABICLOT in patients with severe renal impairment is contraindicated. No dose adjustment is necessary in patients with mild renal impairment. For patients with moderate renal impairment the recommended dose of DABICLOT is also 300 mg taken as one 150 mg capsule twice daily.

**Pediatrics population:** For the indication DVT/PE, the safety and efficacy of DABICLOT in children from birth to less than 18 years of age have not yet been established.

**Method of Administration:** DABICLOT is for oral use. The capsules can be taken with or without food. DABICLOT should be swallowed as a whole with a glass of water, to facilitate delivery to the stomach.

## SPECIAL WARNINGS AND PRECAUTIONS:

**Hemorrhagic risk:** DABICLOT should be used with caution in conditions with an increased risk of bleeding or with concomitant use of medicinal products affecting hemostasis by inhibition of platelet aggregation. Bleeding can occur at any site during therapy with DABICLOT. Risk factors comprise co-medication with platelet aggregation inhibitors such as Clopidogrel and acetylsalicylic acid (ASA) or non-steroidal anti-inflammatory drugs (NSAID).

**Pregnancy:** Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women.

**Breast-feeding:** There are no clinical data of the effect of DABICLOT on infants during breast-feeding.

## CONTRAINDICATIONS:

- Hypersensitivity to the active substance or to any of the excipients

For Further Details:

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Market Planning Department

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## Introducing

**An Effective Anticoagulant  
With  
No Monitoring Required....**





Reduces the risk of Stroke in Non-Valvular Atrial Fibrillation<sup>1</sup>

# DABICLOT

Dabigatran Etexilate 110/ 150 mg Capsule

Superior to **Warfarin**  
at reducing the risk of  
**Stroke<sup>1</sup>**

Requires  
**No Dietary  
Restrictions<sup>1</sup>**

Shows better efficacy than **Warfarin** in  
**Renal Impairment** and **Elderly Patients<sup>2</sup>**

1. New England Journal of Medicine (RE-LY Trial), 2009

2. Thrombosis and Haemostasis, 2017



# DABICLOT

Dabigatran Etexilate 110/ 150 mg Capsule

Significantly reduces the 2 most devastating events for your patient<sup>3</sup>

Intracranial  
Hemorrhage

**59%**

risk reduction  
vs Warfarin<sup>3</sup>

**35%**

risk reduction  
vs Warfarin<sup>3</sup>

Ischemic  
Stroke

**Breaks Down The Hardest Clot**

3. Lancet, 2014






# DABICLOT

Dabigatran Etexilate 110/ 150 mg Capsule

Requires  
**No Regular  
Blood Test<sup>4</sup>**

 **92%**  
RRR of  
Recurrent VTE<sup>5</sup>

## Breaks Down The Hardest Clot

4. Drug Safety, 2011

5. New England Journal of Medicine (RE-SONATE Trial), 2013



Lower HbA1C<sup>2</sup>



Lower the risk  
of CV Death<sup>1</sup>



Without  
Hypoglycemia<sup>2</sup>

## Additional Benefits

**Weight Loss<sup>4</sup>**

**BP Reduction<sup>5</sup>**

### References:

1. *Circulation*. (2016)
2. *New England Journal of Medicine* (2015)
3. *ESC Guidelines* (2019)
4. *ADA Guidelines* (2020)
5. *European Journal of Clinical Pharmacology* (2016)



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# 2 OUT OF 3

DEATHS IN DIABETES,  
ARE DUE TO CVD<sup>1</sup>



## Introducing

The first Type 2 Diabetes pill proven to go beyond lowering HbA1C to **reduce the risk of CV death.....**



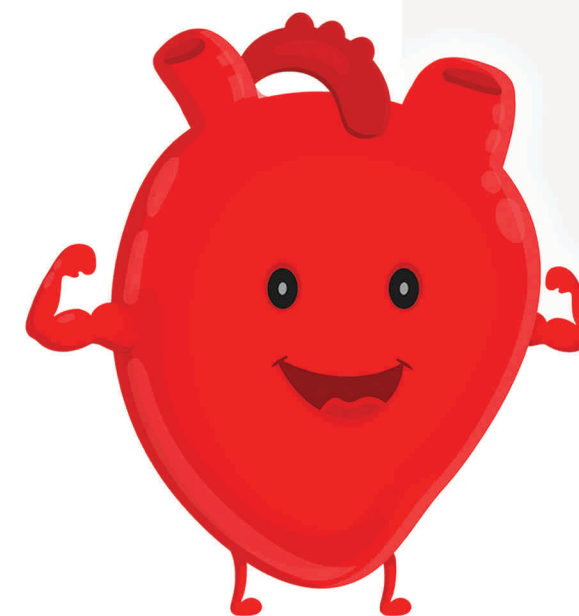


# GLUCOEMP

Empagliflozin 10/ 25 mg Tablet

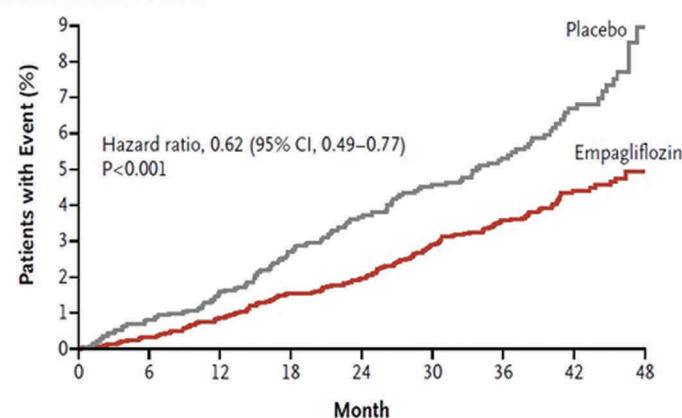
Only oral anti-hyperglycemic agent  
proven to show significant reductions in

**Major Adverse  
Cardiovascular Events  
(MACE)<sup>3</sup>**



↓ **38% Cardiovascular  
Death<sup>2</sup>**

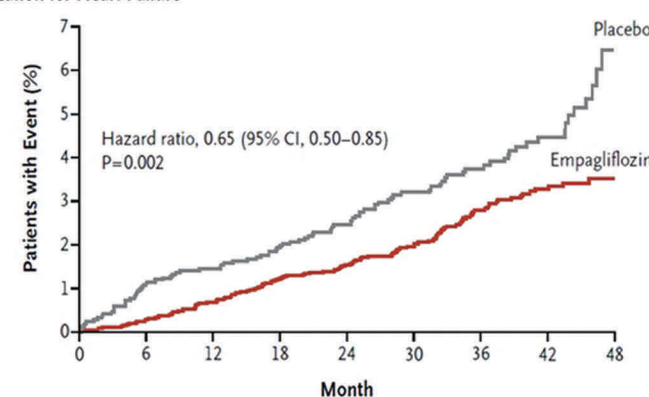
B Death from Cardiovascular Causes



No. at Risk	0	6	12	18	24	30	36	42	48
Empagliflozin	4687	4651	4608	4556	4128	3079	2617	1722	414
Placebo	2333	2303	2280	2243	2012	1503	1281	825	177

↓ **35% Hospitalization  
for Heart Failure<sup>2</sup>**

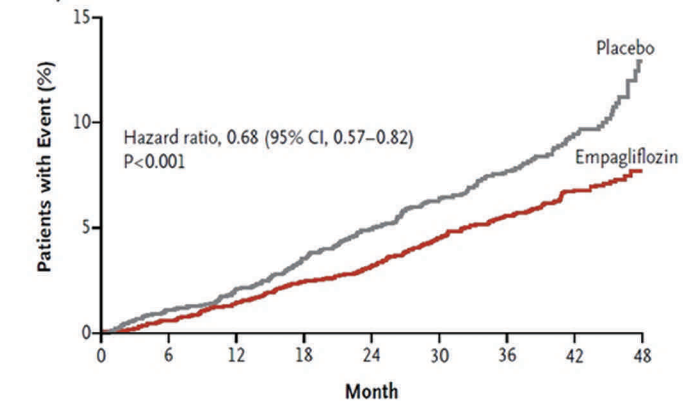
D Hospitalization for Heart Failure



No. at Risk	0	6	12	18	24	30	36	42	48
Empagliflozin	4687	4614	4523	4427	3988	2950	2487	1634	395
Placebo	2333	2271	2226	2173	1932	1424	1202	775	168

↓ **32% Mortality<sup>2</sup>**

C Death from Any Cause



No. at Risk	0	6	12	18	24	30	36	42	48
Empagliflozin	4687	4651	4608	4556	4128	3079	2617	1722	414
Placebo	2333	2303	2280	2243	2012	1503	1281	825	177

Also **14%** reduction in **Cardiovascular Events<sup>2</sup>**



Life can be sweeter with less sugar

