





EMLc

ATC codes: J05AP08

Indication	Chronic hepatitis C ICD11 code: 1E91.1
INN	Sofosbuvir
Medicine type	Chemical agent
List type	Core
Additional notes	Pangenotypic when used in combination with daclatasvir.
Formulations	Oral > Solid: 400 mg ; 200 mg
EML status history	First added in 2015 (TRS 994) Changed in 2019 (TRS 1021) Changed in 2021
Sex	All
Age	Also recommended for children
Therapeutic alternatives	daclatasvir (ATC codes: J05AP07) glecaprevir + pibrentasvir (ATC codes: J05AP57) sofosbuvir + velpatasvir (ATC codes: J05AP55) daclatasvir + sofosbuvir Oral > Solid: 60 mg + 400 mg
Patent information	Main patent is active in several jurisdictions. For more information on specific patents and license status for developing countries visit www.MedsPal.org  Read more about patents. 
Wikipedia	Sofosbuvir 
DrugBank	Sofosbuvir 

Expert Committee recommendation

The Expert Committee recommended the addition of the fixed-dose combination of daclatasvir + sofosbuvir, single-agent daclatasvir and single-agent sofosbuvir to the core list of the EMLc for the treatment of children with chronic HCV infection among patients weighting 14 kg or more, based on evidence of pan-genotypic effectiveness and an acceptable safety profile. The Committee noted that the results of a systematic review of trials, including trials involving daclatasvir and sofosbuvir, demonstrated high rates of virological response in children and adolescents, comparable with those observed in adults. The Committee therefore also recommended that listings of daclatasvir and sofosbuvir on the EML be extended to include adolescents. In addition, the Committee recommended the addition to the EML of the fixed-dose combination of daclatasvir + sofosbuvir and single-agent sofosbuvir 200 mg to the EML for treatment of adolescents and adults. The Committee recognized that in paediatric patients with HCV infection and cirrhosis, co-administration of daclatasvir and sofosbuvir with ribavirin may be required. However, the Committee noted that there was limited evidence on the use of ribavirin in children and the number of children requiring ribavirin co-treatment was very small; therefore, the Committee did not recommend the inclusion of ribavirin on the EMLc. The Committee also noted the planned inclusion of daclatasvir + sofosbuvir as one of the recommended regimens for children in the updated WHO Guidelines for the care and treatment of persons diagnosed with chronic hepatitis C virus infection, the licensing agreements with the Medicines Patent Pool and the availability of prequalified and generic products.

