### Dexamethasone

**Section:** 8. Immunomodulators and antineoplastics  >  8.2. Antineoplastics and supportive medicines  >  8.2.4. Hormones and antihormones

<table>
<thead>
<tr>
<th>Indication</th>
<th>Burkitt lymphoma including Burkitt leukaemia</th>
</tr>
</thead>
<tbody>
<tr>
<td>INN</td>
<td>Dexamethasone</td>
</tr>
<tr>
<td>Medicine type</td>
<td>Chemical agent</td>
</tr>
<tr>
<td>List type</td>
<td>Complementary (EML) (EMLc)</td>
</tr>
<tr>
<td>Formulations</td>
<td>Oral &gt; Liquid: 2 mg per 5 mL (EMLc)</td>
</tr>
<tr>
<td></td>
<td>Oral &gt; Solid: 2 mg (EMLc); 4 mg</td>
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<tr>
<td></td>
<td>Parenteral &gt; General injections &gt; unspecified: 4 mg per mL in 1 mL ampoule (as disodium phosphate salt)</td>
</tr>
<tr>
<td>EML status history</td>
<td>First added in 2021 (TRS 1035)</td>
</tr>
<tr>
<td>Sex</td>
<td>All</td>
</tr>
<tr>
<td>Age</td>
<td>Also recommended for children</td>
</tr>
<tr>
<td>Therapeutic alternatives</td>
<td>The recommendation is for this specific medicine</td>
</tr>
<tr>
<td>Patent information</td>
<td>Patents have expired in most jurisdictions</td>
</tr>
<tr>
<td></td>
<td>Read more about patents.</td>
</tr>
<tr>
<td>Tags</td>
<td>Cancer</td>
</tr>
</tbody>
</table>

**Indications**
- Burkitt lymphoma including Burkitt leukaemia

**Wikipedia**
- Dexamethasone

**DrugBank**
- Dexamethasone

### Expert Committee recommendation

The Expert Committee noted that the incidence of paediatric tumours has been steadily increasing over the past decades with the largest increases reported in youngest children. The Expert Committee recommended the extension of the current listings on the complementary list of the EMLc of the medicines outlined in the following table for the indications specified. Noting that these paediatric cancers also affect older children and adolescents, the Committee also recommended extending the listings for these medicines on the EML. Medicine: (Indication(s)) Carboplatin: (Nephroblastoma, ovarian and testicular germ cell tumours) Cyclophosphamide: (Nephroblastoma) Dactinomycin: (Ewing sarcoma) Dexamethasone: (Burkitt lymphoma) Etoposide: (Acute myeloid leukaemia, nephroblastoma, osteosarcoma) Hydrocortisone: (Burkitt lymphoma) Ifosfamide: (Burkitt lymphoma, nephroblastoma) Imatinib: (Acute lymphoblastic leukaemia) Irinotecan: (Nephroblastoma, rhabdomyosarcoma) Methotrexate: (Burkitt lymphoma) Methylprednisolone: (Burkitt lymphoma) The Committee noted that administration of intravenous cyclophosphamide or ifosfamide required the use of the accompanying medicine mesna to prevent haemorrhagic cystitis commonly associated with these treatments. The Committee therefore also recommended the extension of the current listing for mesna on the EML and EMLc to include the indications of nephroblastoma and Burkitt lymphoma.

### Background

The proposed medicines are all included on the EMLc for other cancer indications.
Cancer is a leading cause of death in children globally; the most common cancer types in children are leukaemias, lymphomas and central nervous system tumours (1). Childhood cancers generally cannot be prevented or screened for, so improving outcomes for children with cancer relies on early and accurate diagnosis and access to effective treatments. In 2018, WHO launched the Global Initiative for Childhood Cancer, to provide leadership and technical assistance to Member States to build and sustain high-quality childhood cancer programmes. The goal of this initiative is to achieve at least 60% survival for all children with cancer globally by 2030 (2).

Cancer in children and adolescents is almost exclusively treated according to national and international treatment protocols. This is the case for first treatment and relapsed and refractory disease. Treatment regimens are devised by clinical experts from relevant tumour groups and are further developments of previous regimens. Often these treatment protocols consist of the standard arm that has proven to be effective based on previous experimental trials. All medicines proposed in this application are part of international treatment regimens and are considered the standard of care. Acute myeloid leukaemia – etoposide Etoposide is included in multiple trial regimens as standard therapy for children with acute myeloid leukaemia, including the AML-BFM 2012 (3), NOPHO-DBH AML 2012 (4) and ML DS 2006 (5) trials. Nephroblastoma – carboplatin, cyclophosphamide, etoposide, ifosfamide, irinotecan Carboplatin, cyclophosphamide, etoposide, ifosfamide and irinotecan are included as chemotherapy interventions along with dactinomycin, doxorubicin, melphalan and vincristine in the SIOP 2001/GPOH (6) and Umbrella SIOP-RTSG 2016 (7) trial regimens for nephroblastoma (Wilms tumour). Acute lymphoblastic leukaemia – imatinib Imatinib is included in the ALLTogether trial regimen for children and young adults with acute lymphoblastic leukaemia (8) and the EsPhALL trial regimen for children with Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukaemia (9).

Chemotherapy is associated with serious adverse events in the acute setting and also in the long term in cancer survivors; it therefore requires close monitoring (25–27). All proposed medicines in this application are already included on the EMLc. Their safety profiles are well known as a result of long-standing experience with their use.

WHO guidelines for the treatment of paediatric cancer are not available. Burkitt lymphoma and nephroblastoma are among the six tracer cancers in the WHO Global Initiative for Childhood Cancer.

The proposed medicines are already included on the EMLc and are available in branded and generic forms.
The EML Cancer Medicines Working Group advised that it supported expansion of the listings on the EMLc for the proposed cancer medicines for the proposed new indications. These medicines are all used in standard, multimodal chemotherapy protocols for the proposed indications. Expanding the EMLc indications for these medicines would support the goals of WHO Global Paediatric Cancer initiative and contribute towards the achievement of the best possible cancer care for children. The Working Group acknowledged that the availability of clinical evidence in the paediatric context was limited but considered that obtaining the usual level of evidence required for EML listings was unlikely. In this case, efficacy and safety could be accepted based on extrapolation of the well known benefits and harms from use of these medicines in adults, for other indications in children and as part of standard cancer care in children.

7. UMBRELLA protocol SIOP-RTSG 2016 – Integrated research and guidelines for standardized diagnostics and therapy of kidney tu
8. A treatment study protocol of the ALLTogether Consortium for Children and Young Adults (1–45 Years of Age) With Newly Diagno
9. Safety and efficacy of imatinib added to chemotherapy in treatment of Ph+ acute lymphoblastic leukaemia in children (ESPALL), B
3: ng’s sarcoma treatment—cyclophosphamide compared with ifosfamide in standard-risk patients and assessment of benefit of eto
11. Combination chemotherapy with or without peripheral stem cell transplantation, radiation therapy, and/or surgery in treating pa
3: 00–500.
3: cell rescue compared with standard chemotherapy in localized high-risk Ewing sarcoma: results of Euro-EW.I.N.G.99 and Ewing-200:
17. Interim guidelines for the treatment of extracranial germ cell tumours in children and adolescents. Leicester: Children’s Cancer a
18. International cooperative trial protocol for children and adolescents with acute myelogenous leukaemia (FAB M4 and M5). Columb:
3: et.