INSTRUCTIONS

Task

Read the following texts describing the specific diseases (called indications) for which a particular drug is suggested. Then, write down all the indications for which the drug is explicitly or implicitly advocated.

Dos

1. Do be as specific as possible. For e.g. if the drug is indicated for a specific type of breast cancer such as medullary breast cancer then write down “medullary breast cancer” and not just “breast cancer”.
2. Do be as resourceful as possible if you need help in understanding the terms in the texts (googling etc.), but don’t let it consume too much of your time.
3. Do feel free to expand on the terms used in the text for the indications, if required. For example, if the text states “…this drug is indicated for patients with diabetes mellitus (types I and II)…”, then do enumerate them: “1. Diabetes Mellitus I, 2. Diabetes Mellitus II”. Do not paste the text as is: “1. Diabetes mellitus (types I and II)”.

Don’ts

1. Don’t write down indications which are not treated by the drug
2. Sometimes an indication appears in the text but it is suggested that the given drug should NOT be used for this indication. Do not write these particular indications of down.
3. While it is encouraged to be as specific as possible, we only want to capture the particular indication (disease) that the drug is suggested for, and not any other contextual information. For example, if the text mentions that the drug should be used in adult patients that have some disease, do not write down “adult patients” as part of the indication.
4. Some drugs treat conditions that either: arise out of other conditions, or are associated with / not associated with other conditions. The condition that the drug treats directly is called the “primary indication” and any other conditions linked to this primary indication are known as “secondary indications”. Do not write down the secondary indications. Only write down the primary indication.

Examples

ROSUVASTATIN

**Indications and usage text**

“use information for patients 7 to 17 years of age is approved for AstraZeneca’s CRESTOR (rosuvastatin calcium) tablets. However, due to AstraZeneca’s marketing exclusivity rights, this drug product is not labeled with that pediatric information.

1.3 Hypertriglyceridemia

Rosuvastatin calcium tablets are indicated as adjunctive therapy to diet for the treatment of adult patients with hypertriglyceridemia.

1.4 Primary Dysbetalipoproteinemia (Type III Hyperlipoproteinemia)

Rosuvastatin calcium tablets are indicated as an adjunct to diet for the treatment of adult patients with primary dysbetalipoproteinemia (Type III Hyperlipoproteinemia).

1.5 Adult Patients with Homozygous Familial Hypercholesterolemia

Rosuvastatin calcium tablets are indicated as adjunctive therapy to other lipid-lowering treatments (e.g., LDL apheresis) or alone if such treatments are unavailable to reduce LDL-C, Total-C, and ApoB in adult patients with homozygous familial hypercholesterolemia.

1.8 Limitations of Use

Rosuvastatin calcium tablets have not been studied in Fredrickson Type I and V dyslipidemias.”

**Indications**

1. Hypertriglyceridemia
2. Primary Dysbetalipoproteinemia
3. Type III Hyperlipoproteinemia
4. Homozygous Familial Hypercholesterolemia

PROPAFENONE

**Indications and usage text**

“Propafenone hydrochloride is indicated to:

prolong the time to recurrence of paroxysmal atrial fibrillation/flutter (PAF) associated with disabling symptoms in patients without structural heart disease.

prolong the time to recurrence of paroxysmal supraventricular tachycardia (PSVT) associated with disabling symptoms in patients without structural heart disease.

treat documented ventricular arrhythmias, such as sustained ventricular tachycardia that, in the judgment of the physician, are life-threatening. Initiate treatment in the hospital.

Usage Considerations:

The use of propafenone hydrochloride tablets in patients with permanent atrial fibrillation (AF) or in patients exclusively with atrial flutter or PSVT has not been evaluated. Do not use propafenone hydrochloride tablets to control ventricular rate during AF.

Some patients with atrial flutter treated with propafenone have developed 1:1 conduction, producing an increase in ventricular rate. Concomitant treatment with drugs that increase the functional atrioventricular (AV) nodal refractory period is recommended.

The use of propafenone hydrochloride tablets in patients with chronic atrial fibrillation has not been evaluated.

Because of the proarrhythmic effects of propafenone hydrochloride, its use with lesser ventricular arrhythmias is not recommended, even if patients are symptomatic, and any use of the drug should be reserved for patients in whom, in the opinion of the physician, the potential benefits outweigh the risks.

The effect of propafenone on mortality has not been determined.”

**Indications**

1. Paroxysmal atrial fibrillation
2. Paroxysmal atrial flutter
3. Paroxysmal supraventricular tachycardia
4. Ventricular arrhythmia
5. Sustained ventricular tachycardia

Test Cases

MECAMYLAMINE

**Indications and usage text**

“For the management of moderately severe to severe essential hypertension and in uncomplicated cases of malignant hypertension.”

**Indications**

1. Moderately severe essential hypertension
2. Severe essential hypertension
3. Malignant hypertension / uncomplicated cases of malignant hypertension

CARMUSTINE

**Indications and usage text**

“GLIADEL® Wafer is indicated in newly-diagnosed high-grade malignant glioma patients as an adjunct to surgery and radiation. GLIADEL® Wafer is indicated in recurrent glioblastoma multiforme patients as an adjunct to surgery.”

**Indications**

1. High-grade malignant glioma
2. Glioblastoma multimforme / Recurrent glioblastoma multiforme

CARVEDILOL\*

**Indications and usage text**

“1.1 Left Ventricular Dysfunction following Myocardial Infarction

Carvedilol is indicated to reduce cardiovascular mortality in clinically stable patients who have survived the acute phase of a myocardial infarction and have a left ventricular ejection fraction of ≤40% (with or without symptomatic heart failure) [see Clinical Studies (14.1)].

1.2 Hypertension

Carvedilol is indicated for the management of essential. It can be used alone or in combination with other antihypertensive agents, especially thiazide-type diuretics [see Drug Interactions (7.2)].”

**Indications**

1. Left Ventricular Dysfunction following Myocardial Infarction
2. Left Ventricular Dysfunction
3. Hypertension
4. Essential hypertension

**\* Typo in 1.2 Hypertension – essential hypertension**

AMILORIDE

**Indications and usage text**

“Amiloride hydrochloride and hydrochlorothiazide tablets are indicated in those patients with hypertension or with congestive heart failure who develop hypokalemia when thiazides or other kaliuretic diuretics are used alone, or in whom maintenance of normal serum potassium levels is considered to be clinically important, e.g., digitalized patients, or patients with significant cardiac arrhythmias.

The use of potassium-conserving agents is often unnecessary in patients receiving diuretics for uncomplicated essential hypertension when such patients have a normal diet.

Amiloride hydrochloride and hydrochlorothiazide tablets may be used alone or as an adjunct to other antihypertensive drugs, such as methyldopa or beta blockers. Since amiloride hydrochloride and hydrochlorothiazide enhances the action of these agents, dosage adjustments may be necessary to avoid an excessive fall in blood pressure and other unwanted side effects.

This fixed combination drug is not indicated for the initial therapy of edema or hypertension except in individuals in whom the development of hypokalemia cannot be risked.”

**Indications**

1. Hypertension
2. Congestive heart failure
3. Cardiac arrhythmia

AZACITIDINE

**Indications and usage text**

“1.1 Myelodysplastic Syndromes (MDS)

Azacitidine for injection is indicated for treatment of patients with the following French-American-British (FAB) myelodysplastic syndrome subtypes: refractory anemia (RA) or refractory anemia with ringed sideroblasts (if accompanied by neutropenia or thrombocytopenia or requiring transfusions), refractory anemia with excess blasts (RAEB), refractory anemia with excess blasts in transformation (RAEB-T), and chronic myelomonocytic leukemia (CMMoL).”

**Indications**

1. Myelodysplastic Syndromes
2. Refractory anemia
3. Refractory anemia with ringed sideroblasts
4. Refractory anemia with excess blasts
5. Refractory anemia with excess blasts in transformation
6. Chronic myelomonocytic leukemia

BLEOMYCIN

**Indications and usage text**

“Bleomycin for Injection, USP should be considered a palliative treatment.  It has been shown to be useful in the management of the following neoplasms either as a single agent or in proven combinations with other approved chemotherapeutic agents:

Squamous Cell Carcinoma: Head and neck (including mouth, tongue, tonsil, nasopharynx, oropharynx, sinus, palate, lip, buccal mucosa, gingivae, epiglottis, skin, larynx), penis, cervix, and vulva.  The response to Bleomycin for Injection is poorer in patients with previously irradiated head and neck cancer.

Lymphomas: Hodgkin’s disease, non-Hodgkin’s lymphoma.

Testicular Carcinoma: Embryonal cell, choriocarcinoma, and teratocarcinoma.

Bleomycin for Injection, USP has also been shown to be useful in the management of:

Malignant Pleural Effusion: Bleomycin for Injection is effective as a sclerosing agent for the treatment of malignant pleural effusion and prevention of recurrent pleural effusions.”

**Indications**

1. Squamous Cell Carcinoma
2. Squamous Cell Carcinoma of the head and neck
3. Squamous Cell Carcinoma of the mouth
4. Squamous Cell Carcinoma of the tongue
5. Squamous Cell Carcinoma of the tonsil
6. Squamous Cell Carcinoma of the nasopharynx
7. Squamous Cell Carcinoma of the oropharanyx
8. Squamous Cell Carcinoma of the sinus
9. Squamous Cell Carcinoma of the palate
10. Squamous Cell Carcinoma of the lip
11. Squamous Cell Carcinoma of the buccal mucosa
12. Squamous Cell Carcinoma of the gingivae
13. Squamous Cell Carcinoma of the epiglottis
14. Squamous Cell Carcinoma of the skin
15. Squamous Cell Carcinoma of the larynx
16. Squamous Cell Carcinoma of the penis
17. Squamous Cell Carcinoma of the cervix
18. Squamous Cell Carcinoma of the vulva
19. Lymphoma
20. Hodgkin’s disease
21. Non-hodgkin’s lymphoma
22. Testicular Carcinoma
23. Embryonal cell carcinoma
24. Choriocarcinoma
25. Teratocarcinoma of the testis
26. Malignant Pleural Effusion

Actual Tasks

METHYL AMINOLEVULINATE

**Indications and usage text**

“Metvixia Cream in combination with 570 to 670 nm wavelength red light illumination using the CureLight BroadBand Model CureLight 01 lamp is indicated for treatment of non-hyperkeratotic actinic keratoses of the face and scalp in immunocompetent patients when used in conjunction with lesion preparation (debridement using a sharp dermal curette) in the physician’s office when other therapies are unacceptable or considered medically less appropriate.”

**Indications**

1. Non-hyperkeratotic actinic keratoses of the face
2. Non-hyperkeratotic actinic keratoses of the scalp

DOXORUBICIN

**Indications and usage text**

“1.1 Adjuvant Breast Cancer

Doxorubicin HCl for injection is indicated as a component of multi-agent adjuvant chemotherapy for treatment of women with axillary lymph node involvement following resection of primary breast cancer.

1.2 Other Cancers

Doxorubicin HCl for injection is indicated for the treatment of:

acute lymphoblastic leukemia

acute myeloblastic leukemia

Hodgkin lymphoma

non-Hodgkin lymphoma (NHL)

metastatic breast cancer

metastatic Wilms’ tumor

metastatic neuroblastoma

metastatic soft tissue sarcoma

metastatic bone sarcoma

metastatic ovarian carcinoma

metastatic transitional cell bladder carcinoma

metastatic thyroid carcinoma

metastatic gastric carcinoma

metastatic bronchogenic carcinoma”

**Indications**

1. Axillary lymph node involvement / Axillary lymph node involvement following resection of primary breast cancer
2. Acute lymphoblastic leukemia
3. Acute myeloblastic leukemia
4. Hodgkin’s lymphoma
5. Non-Hodgkin’s lymphoma
6. Metastatic breast cancer
7. Metastatic Wilms’ tumor
8. Metastatic neuroblastoma
9. Metastatic soft tissue sarcoma
10. Metastatic bone sarcoma
11. Metastatic ovarian carcinoma
12. Metastatic transitional cell bladder carcinoma
13. Metastatic thyroid carcinoma
14. Metastatic gastric carcinoma
15. Metastatic bronchogenic carcinoma

BUSULFAN

**Indications and usage text**

“BUSULFEX® (busulfan) Injection is indicated for use in combination with cyclophosphamide as a conditioning regimen prior to allogeneic hematopoietic progenitor cell transplantation for chronic myelogenous leukemia.”

**Indications**

1. Chronic myelogenous leukemia.

TOPOTECAN

**Indications and usage text**

“Topotecan Hydrochloride for Injection is indicated for the treatment of:

small cell lung cancer sensitive disease after failure of first-line chemotherapy. In clinical studies submitted to support approval, sensitive disease was defined as disease responding to chemotherapy but subsequently progressing at least 60 days (in the Phase 3 study) or at least 90 days (in the Phase 2 studies) after chemotherapy. [see Clinical Studies ([14](https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=715620fb-614f-40b6-8d3d-8494843d8518#i4i_clinical_studies_id_5876acb6-1f8d-463d-9895-3836aa7736ff))].

Topotecan Hydrochloride for Injection in combination with cisplatin is indicated for the treatment of:

stage IV-B, recurrent, or persistent carcinoma of the cervix which is not amendable to curative treatment with surgery and/or radiation therapy.”

**Indications**

1. Small cell lung cancer / Small cell lung cancer sensitive disease
2. Stage IV-B carcinoma of the cervix
3. Recurrent carcinoma of the cervix
4. Persistent carcinoma of the cervix

MELPHALAN

**Indications and usage text**

“Melphalan Tablets USP are indicated for the palliative treatment of multiple myeloma and for the palliation of non-resectable epithelial carcinoma of the ovary.”

**Indications**

1. Multiple myeloma
2. Non-resectable epithelial carcinoma of the ovary

FLUDARABINE

**Indications and usage text**

“Fludarabine Phosphate for Injection, USP is indicated for the treatment of patients with B-cell chronic lymphocytic leukemia (CLL) who have not responded to or whose disease has progressed during treatment with at least one standard alkylating-agent containing regimen.  The safety and effectiveness of Fludarabine Phosphate for Injection, USP in previously untreated or non-refractory patients with CLL have not been established.”

**Indications**

1. B-cell chronic lymphocytic leukemia

CAPECITABINE

**Indications and usage text**

“1.1 Colorectal Cancer

Capecitabine tablets are indicated as a single agent for adjuvant treatment in patients with Dukes’ C colon cancer who have undergone complete resection of the primary tumor when treatment with fluoropyrimidine therapy alone is preferred. Capecitabine tablets were non-inferior to 5-fluorouracil and leucovorin (5-FU/LV) for disease-free survival (DFS). Physicians should consider results of combination chemotherapy trials, which have shown improvement in DFS and OS, when prescribing single-agent capecitabine tablets in the adjuvant treatment of Dukes’ C colon cancer.

Capecitabine tablets are indicated as first-line treatment of patients with metastatic colorectal carcinoma when treatment with fluoropyrimidine therapy alone is preferred. Combination chemotherapy has shown a survival benefit compared to 5-FU/LV alone. A survival benefit over 5-FU/LV has not been demonstrated with capecitabine tablets monotherapy. Use of capecitabine tablets instead of 5-FU/LV in combinations has not been adequately studied to assure safety or preservation of the survival advantage.

1.2 Breast Cancer

Capecitabine tablets in combination with docetaxel are indicated for the treatment of patients with metastatic breast cancer after failure of prior anthracycline-containing chemotherapy.

Capecitabine tablets monotherapy is also indicated for the treatment of patients with metastatic breast cancer resistant to both paclitaxel and an anthracycline-containing chemotherapy regimen or resistant to paclitaxel and for whom further anthracycline therapy is not indicated (e.g., patients who have received cumulative doses of 400 mg/m2 of doxorubicin or doxorubicin equivalents). Resistance is defined as progressive disease while on treatment, with or without an initial response, or relapse within 6 months of completing treatment with an anthracycline-containing adjuvant regimen.”

**Indications**

1. Colorectal Cancer
2. Dukes’ C colon cancer
3. Metastatic colorectal carcinoma
4. Breast Cancer
5. Metastatic breast cancer

PROCARBAZINE

**Indications and usage text**

“Matulane is indicated for use in combination with other anticancer drugs for the treatment of Stage III and IV Hodgkin's disease. Matulane is used as part of the MOPP (nitrogen mustard, vincristine, procarbazine, prednisone) regimen.”

**Indications**

1. Stage III Hodgkin’s disease
2. Stage IV Hodgkin’s disease

IDARUBICIN

**Indications and usage text**

“Idarubicin hydrochloride injection in combination with other approved antileukemic drugs is indicated for the treatment of acute myeloid leukemia (AML) in adults. This includes French-American-British (FAB) classifications M1 through M7.”

**Indications**

1. Acute myeloid leukemia
2. Acute myeloblastic leukemia with minimal maturation (M1)
3. Acute myeloblastic leukemia with maturation (M2)
4. Acute promyelocytic leukemia (M3)
5. Acute myelomonocytic leukemia (M4)
6. Acute myelomonocytic leukemia with eosinophilia (M4 eos)
7. Acute monocytic leukemia (M5)
8. Acute erythroid leukemia (M6)
9. Acute megakaryoblastic leukemia (M7)

IFOSFAMIDE

**Indications and usage text**

“Ifosfamide for Injection is indicated for use in combination with certain other approved antineoplastic agents for third-line chemotherapy of germ cell testicular cancer. It should be used in combination with mesna for prophylaxis of hemorrhagic cystitis.”

**Indications**

1. Germ cell testicular cancer
2. Hemorrhagic cystitis