**TEMPLATE**

**PHARMACY & THERAPEUTICS COMMITTEE**

DRUG EVALUATION – SUMMARY PAGE

**Drug Name**: generic (Brand®)

**Manufacturer:**

**Therapeutic Class:**

**Similar Agents:**

**REMS:** Yes, No [if yes, indicate medication guide, certification program etc.]

**Boxed Warning**: Yes/No, If yes, include boxed warning

**Date FDA Approved:**

**Executive Summary:**

**Recommendations:**

**PHARMACY & THERAPEUTICS COMMITTEE**

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**Date FDA Approved:**

**Table 1: Products in Class**

|  |  |  |  |
| --- | --- | --- | --- |
| **Generic** | **Brand** | **Manufacturer** | **FDA Approval** |
|  |  |  |  |
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**INDICATIONS:**

Table 2: FDA Labeled Indications:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Drug | Indication(s) |  |  |  |
|  |  |  |  |  |
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**BACKGROUND:**

Include brief disease state background and any information on any other treatment options (if they exist).

**CLINICAL PHARMACOLOGY:**

**PHARMACOKINETICS:**

**Table 3,**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Parameters** | **Generic Drug Name** |  |  |  |  |
| **Dose (mg/day)** |  |  |  |  |  |
| **Bioavailability** |  |  |  |  |  |
| **Absorption** |  |  |  |  |  |
| **Time to peak concentration** |  |  |  |  |  |
| **Plasma binding** |  |  |  |  |  |
| **Volume of distribution** |  |  |  |  |  |
| **Effect of food** |  |  |  |  |  |
| **Active metabolite (s)** |  |  |  |  |  |
| **Protein binding** |  |  |  |  |  |
| **Half-life** |  |  |  |  |  |
| **Excretion** |  |  |  |  |  |
| **CYP Substrate** |  |  |  |  |  |

CLINICAL STUDIES:

[In this section, include a small paragraph outlining the total number of trials you identified, indicate the types of studies and focus on the highest quality. This will help the reader understand the total volume of articles available on the drug, which was the highest quality and why you chose the ones you did. Rank in order of (1) comparative efficacy (2) randomized controlled trials (3) placebo-controlled trials; include the most key pivotal trials and include quality of life data if available for high cost, low-to medium impact drugs]

## COMPARATIVE EFFICACY TRIALS (if available)

|  |  |  |
| --- | --- | --- |
| Citation | | |
| **Design** | **Methods** | **Results** |
| R, DB, PC?  [Published]  **Duration of Study:**  **Study Size:**  **Purpose:** | **Inclusion Criteria:**  **Exclusion Criteria:**  **Primary Endpoint:**  **Secondary Endpoints:**  **Definitions:**  **Treatment Groups:**  **1.**  **2.**  **3.** | **Primary Endpoints:**  **Secondary Endpoints:**  **Adverse Effects:**  **Limitations:**  **Conclusion:** |

**Pivotal Randomized Controlled Trials (if available)**

|  |  |  |
| --- | --- | --- |
| Citation | | |
| **Design** | **Methods** | **Results** |
| R, DB, PC?  [Published]  **Duration of Study:**  **Study Size:**  **Purpose:** | **Inclusion Criteria:**  **Exclusion Criteria:**  **Primary Endpoint:**  **Secondary Endpoints:**  **Definitions:**  **Treatment Groups:**  **1.**  **2.**  **3.** | **Primary Endpoints:**  **Secondary Endpoints:**  **Adverse Effects:**  **Limitations:**  **Conclusion:** |

**Placebo Controlled Trials (if available)**

|  |  |  |
| --- | --- | --- |
| Citation | | |
| **Design** | **Methods** | **Results** |
| [Published]  **Duration of Study:**  **Study Size:**  **Purpose:** | **Inclusion Criteria:**  **Exclusion Criteria:**  **Primary Endpoint:**  **Secondary Endpoints:**  **Definitions:**  **Treatment Groups:**  **1.**  **2.**  **3.** | **Primary Endpoints:**  **Secondary Endpoints:**  **Adverse Effects:**  **Limitations:**  **Conclusion:** |

**LEGEND:** RCT=Randomized controlled trial, DB=double-blind

**GUIDELINES (IF ANY):**

## CONTRAINDICATIONS/WARNINGS: Table is not required; each drug may have unique features that may not require a table

**BOXED WARNING(S):**

**REMS:**

**ISMP ALERTS:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Contraindications** | | | **Warnings** | | |
|  | **Known Hypersensitivity** | **In Women** | **In Children** | **Pregnancy** | **Hepatic** | **Renal** |
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**PRECAUTIONS:**

**ADVERSE EFFECTS:**

## Table is not always required; each drug may have unique features that may not require a table

**Table:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Drug Brand Name (bold)** | **Drug** |  |  |  |  |  |
|  | n(%) |  |  |  |  |  |
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**DRUG INTERACTIONS:** Note: some drugs require a table; other drugs may not have many drug interactions, and therefore text may be more appropriate.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Drug Brand Name (bold)** | **Drug** |  |  |  |  |  |
|  |  |  |  |  |  |  |
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**PRODUCT AVAILABILITY:**

**DOSING:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Trade Name** | **Strength (s)** | **Usual Starting Dose** | **Maximum dosage** | **Special Instructions** |
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**COST:**

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| --- | --- | --- |
| **Trade Name** | **AWP (Redbook Cost)** | **Cost/month supply** |
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**CONCLUSION(S):**

**RECOMMENDATION:**

**Add**

**Add with restrictions (include details regarding restrictions)**

**Do not add**

**Do not add and ban**

**REFERENCES**