

TOPICAL CIDOFOVIR COMPOUNDING CREAM FOR THE TREATMENT OF DISSEMINATED INFECTION BY MOLLUSCUM CONTAGIOSUM

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BACKGROUND

Cidofovir is a broad-spectrum antiviral agent with activity against several DNA viruses. In Portugal, it has to be imported but it has european medicines agency's approval to treat cytomegalovirus retinitis in specific patient conditions. A sixty-eight-year-old male patient, diagnosed with disseminated infection by molluscum contagiosum, with idiopathic acquired immunodeficiency CD4+ T-cells and pulmonary cryptococcosis treated three years ago, presented with severe erythroderma. He exhibited countless cutaneous lesions, characterized by severe pruritic millimeter papules which affected the majority of his body impairing patient's life quality. The case was refractory to all on-label available therapies and has been prescribed topical cidofovir.

OBJECTIVES

To share procedures followed after the prescription of a new off-label compounded drug: information research and development of specific procedures for this type of hazardous formulation .

Evaluation of treatment effectiveness, three months after the topical cidofovir application in the lower right member.

MATERIAL AND METHODS

Bibliographic research.

Prescription submission for approval of ethics committee for health and clinical board of the hospital. Elaboration of master formula sheet and parameterization off labeling information.

Clinical evaluation and photographic register.

RESULTS

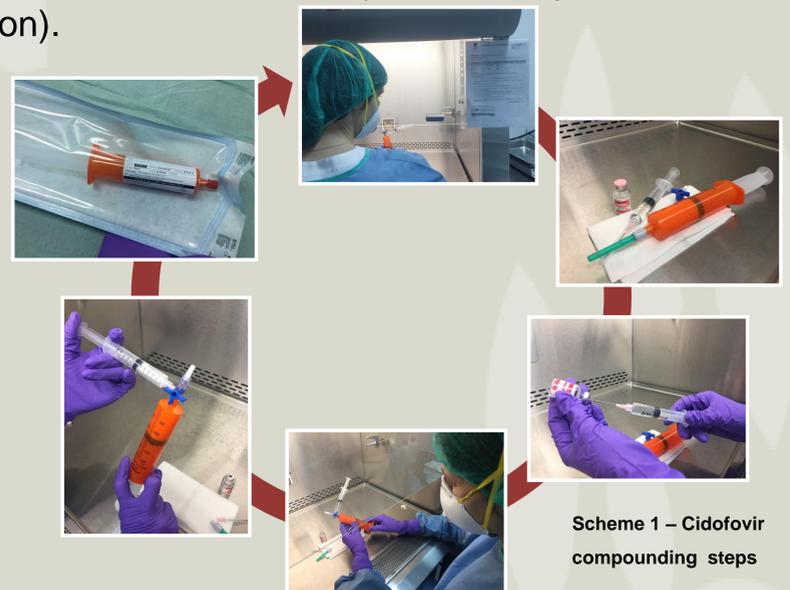
Numerous studies substantiate the prescription, which led to its approval by the referred hospital boards. Cidofovir 3% cream was compounded from injectable cidofovir (Vistidine®) and incorporated into commercially available fat cream (lipolium®). Due to cidofovir's mutagenic properties and its associated risk by exposure, this preparation was performed with proper protection equipment and using luer-lock system (syringes and connectors). After three months of treatment, topical cidofovir proved to be effective, as the patient presented with reduced number of lesions and less evidence of pruritus. He referred no symptoms of local irritation (the most reported adverse reaction).

Ficha Técnica de Preparação		Impressão	
Preparação: Cidofovir 3% Creme tóxico Bisen 50 g - 80003599		Data Hora	2019-03-13 11:19
N.º da Guia/Lote: GP2019030182		Impressão	1/2/198
Quantidade a preparar: 1		Página	1/2
Data de preparação: 13-03-2019 11:18			
Matérias-primas	Origem	N.º Lote / Prato Valid.	Quantidade Calculada
Cidofovir 75 mg/ml Sol n.º 17 / 5 ml IV	VEP Clinical (VZ Pharma LTD)	VCA4555 2020-11-30	25 ml
lip Cream graxo ml (Lipolium)	FUNDOS DE MADEO	49338 2021-04-30	30 g/sem
Equipamento			
CFLV, EPI, balança, seringa opaca 50ml luer-lock, seringa 50ml luer-lock, tomara 3 vias, obturador.			
Técnica de Preparação			
1. Preparação a realizar em CFLV, com EPI adequado: bata, máscara P3 e luvas de nitrilo.			
2. Na LUPME, pesar o creme em seringa luer-lock com proteção da luz, tarando a mesma previamente.			
3. Colocar torneira de 3 vias para fecho da mesma.			
4. Colocar em tabuleiro com restante material, matérias-primas, PTP e rótulos.			
5. Em CFLV medir, em seringa luer-lock, volume de cidofovir necessário. Conectar a seringa com cidofovir à torneira de 3 vias.			
6. Transferir volume de cidofovir para seringa com o creme e vice-versa, através da conexão torneira de 3 vias, até obtenção de um creme aquoso de textura homogênea.			
7. Colocar obturador para fecho. O creme de cidofovir deverá ficar em seringa opaca, que funcionará como acondicionamento.			
8. Rotular e colocar em manga, como acondicionamento secundário			
9. Ampolas e todo o material usado deverão ser colocados em contentor grupo IV (contentor cortantes existente na CFLV).			
		Rubrica do Operador	

Ficha Técnica de Preparação		Impressão	
Material de embalagem		Capacidade	N.º do lote
SERINGA		50GRAM	
Rubrica do Operador			
Serviço			
12310 - CEX DERMATOLOGIA			
Prazo de utilização e condições de conservação			
Condições de conservação: TEMP. AMBIENTE, PROTEGIDO LUZ			
Prazo de utilização: 30 dias; Prazo Validade: 2019-04-12			
Verificação			
Ensaio	Especificação	Resultado	Rubrica do Operador
Cor	Branco		
Aspecto	Mistura cremosa homogênea		
Conform. Prod. com rotulado	Conforme		
Verif. Enq. Otimização	Conforme		
Aprovado <input type="checkbox"/> Rejeitado <input type="checkbox"/>		Supervisor: _____	
Observações			
Cidofovir: Medicamento considerado perigoso para manipular.			
CES/DQ: autorizado para CONIS DERM doente ND: 15009907.			
		Rubrica do Diretor Técnico	Data

Centro Hospitalar de São João, EPE - Serviços Farmacéuticos - Dir. Tto. Dr Paulo			
Depto: CEX DERMATOLOGIA			
Receita: 2019-04-12	Lote/Guia: GP2019030182	Data prep: 2019-03-13	
N.º Adm: TOPICA Volume: 50 GRAMA Potologia:			
Conservação: TEMP. AMBIENTE, PROTEGIDO LUZ			
Obs: LUCI TOPICA PARA PREVENÇÃO/CONTROLO DE LESÕES DE MANIPULAÇÃO MANTER FORA DO ALCANCE DAS CRIANÇAS			
Cidofovir 3% Creme tóxico Bisen 50 g			
Cidofovir 75 mg/ml Sol Inj Ft 6 ml IV	20ML		
lip Cream graxo ml (Lipolium)	30GRAM		

Images 1, 2 – Master Formula Sheet;
Image 3 – Labeling information;



Scheme 1 – Cidofovir compounding steps



Image 4 – Before treatment: countless pruritic cutaneous lesions

Image 5 – After three months of treatment: reduced number of lesions and less evidence of pruritus

CONCLUSIONS

Off-label therapeutic options should be reserved only for specific cases. However, as long as there are no topical options available, compounding pharmacist can be essential, providing an effective and safe formulation.

Operator's safety should not be neglected, and the preparation must be carried out with appropriate precautions/protetion equipment.

It should be noted that the success of this treatment required the commitment of a multidisciplinary team, with consequent improvement of patient's life quality.



<http://www.eahp.eu/24-3PC-012>

Abstract number: 3PC-012
ATC CODE: D11 Other dermatological preparations